(b) (5)

[redacted]

I'd like to discuss this with you all ASAP – momentum will be needed here. I promised to draft a note to the Heverites with the next plan, and to run that draft past Patrick, Paul, and (b) before sending to the rest of the group. I'd like to do that as soon as tomorrow.

Could you all be available for a phone call at 8 AM tomorrow (Monday 4/10)?

Francis

From: Wholley, David (FNIH) [T]
Sent: Wed, 7 Jun 2017 18:00:57 -0400
To: Collins, Francis (NIH/OD) [E]
Subject: Re: Partnership for Accelerating Cancer Therapies

Understand completely. Shall I at least send out the Cardon reponses to the rest of the EC in the event you won't have time to read them? I am heading to an AMP T2D meeting at ADA in San Diego tomorrow morning and want to be sure we get the EC something before the weekend. I do think the summary is fine as written. Thanks, David
Sent from my BlackBerry 10 smartphone.

From: Collins, Francis (NIH/OD) [E]
Sent: Wednesday, June 7, 2017 5:51 PM
To: Wholley, David (FNIH) [T]
Subject: RE: Partnership for Accelerating Cancer Therapies

I have more news on the WH interest. But I'm crashing right now on getting ready for ACD tomorrow, will convey soon…

From: Wholley, David (FNIH) [T]
Sent: Wednesday, June 07, 2017 5:51 PM
To: Collins, Francis (NIH/OD) [E] (b) (6)
Subject: FW: Partnership for Accelerating Cancer Therapies

Hi Francis -- Would you like me to follow this one up or? (b) (5) I have sent Rebecca an update on the other conversations for your meeting Friday. David

---

From: Collins, Francis (NIH/OD) [E]
Sent: Saturday, May 06, 2017 7:13 AM
To: (b) (4), (b) (6)
Cc: Wholley, David (FNIH) [T] <dwholley@fnih.org>
Subject: Partnership for Accelerating Cancer Therapies

Dear (b) (4):

It was a pleasure to meet you at the Milken LA meeting, and I'm glad we got a chance to talk about the Partnership for Accelerating Cancer Therapies (PACT), which we have been developing with multiple pharmaceutical companies and FDA over the last eight months or so. As we discussed, PACT is focused on the critical issue of developing better biomarkers for selecting and testing cancer immunotherapies and relevant combinations. Following up your request for more information, I have attached a text executive summary and a slide deck overviewing the partnership, as well as the full text of the white paper that contains the initial research plan for those who may need more detail.

(b) (4)

(b) (4)

All the best, Francis

From: Wholley, David (FNIH) [T]
Sent: Mon, 8 May 2017 17:21:11 -0400
To: Collins, Francis (NIH/OD) [E];Adam, Stacey (FNIH) [T]
Cc: Baker, Rebecca (NIH/OD) [E];Lowy, Douglas (NIH/NCI) [E];Doroshow, James (NIH/NCI) [E]
Subject: RE: Partnership for Accelerating Cancer Therapies

Thanks Francis. While we have the opportunity here is a brief update for all of what else has occurred since our meeting a little over a week ago:

- We sent out the reminder note to everyone as agreed.
- We heard just this morning from Jeff Ecsedy that Takeda will not participate in PACT. Too many other competing investments, not enough budget, etc.
- We had a good call with Jeff Engelman 4/28 about Novartis's participation. He'd not heard about HEVER, so we filled him in. He will connect with Vas Narasimhan. Given how Novartis R&D is structured, he and Vas are the two people who will make the recommendation to the CEO about whether to do PACT.
- B-I has assigned a new primary contact (Alexander Ehlgen, in their translational medicine group) to work with us on PACT. We think this is a positive sign, based on the note we received. Speaking to him end of this week.
- GSK has assigned a business development person to work with us on contracts, etc.; however although moving in right direction they clearly have not yet completed internal review on whether or not to formally make a commitment to PACT.
- We went back to Bill Chin as planned and he's agreed to a cut-down proposal for PhRMA to participate: he will provide FNIH with $50K to underwrite two PACT face to face meetings at least in the first year; will get a mention in the press release but no role in governance. He needs to leave the arrangement open for yearly renewal since he will be retiring from PhRMA by the end of this year and does not want to bind his successor to anything.
- Ramy Ibrahim is interested in meeting with Stacey and me sometime after ASCO (week of June 5).

From: Collins, Francis (NIH/OD) [E]
Sent: Monday, May 08, 2017 4:06 PM
To: Wholley, David (FNIH) [T] <dwholley@fnih.org>; Adam, Stacey (FNIH) [T] <sadam@fnih.org>
Cc: Baker, Rebecca (NIH/OD) [E] (b) (6); Lowy, Douglas (NIH/NCI) [E] (b) (6); Doroshow, James (NIH/NCI) [E] (b) (6)
Subject: FW: Partnership for Accelerating Cancer Therapies

FYI

From: (b) (4), (b) (6)
Sent: Monday, May 08, 2017 7:29 AM
To: Collins, Francis (NIH/OD) [E] (b) (6)
Subject: RE: Partnership for Accelerating Cancer Therapies

Dear Francis,

Indeed it was great to meet you and share perspectives about the opportunities and challenges facing the U.S. healthcare ecosystem.

Thank you for sending information regarding the "PACT" program. Along with my team, we will review and respond again soon.

All the best,

(b) (4), (b) (6)

From: Collins, Francis (NIH/OD) [E] (b) (6)
Sent: Saturday, May 06, 2017 7:13 AM
To: (b) (4), (b) (6)
Cc: Wholley, David (FNIH) [T] <dwholley@fnih.org>
Subject: Partnership for Accelerating Cancer Therapies

Dear (b) (4):

It was a pleasure to meet you at the Milken LA meeting, and I'm glad we got a chance to talk about the Partnership for Accelerating Cancer Therapies (PACT), which we have been developing with multiple pharmaceutical companies and FDA over the last eight months or so. As we discussed, PACT is focused on the critical issue of developing better biomarkers for selecting and testing cancer immunotherapies and relevant combinations. Following up your request for more information, I have attached a text executive summary and a slide deck overviewing the partnership, as well as the full text of the white paper that contains the initial research plan for those who may need more detail.

(b) (4)

All the best, Francis

****
THIS ELECTRONIC MAIL MESSAGE AND ANY ATTACHMENT IS CONFIDENTIAL AND MAY CONTAIN LEGALLY PRIVILEGED INFORMATION INTENDED ONLY FOR THE USE OF THE INDIVIDUAL OR INDIVIDUALS NAMED ABOVE.
If the reader is not the intended recipient, or the employee or agent responsible to deliver it to the intended recipient, you are hereby notified that any dissemination, distribution or copying of this communication is strictly prohibited. If you have received this communication in error, please reply to the

sender to notify us of the error and delete the original message. Thank You.

From: Wholley, David (FNIH) [T]
Sent: Wed, 28 Jun 2017 18:05:09 -0400
To: Mark Alles;Collins, Francis (NIH/OD) [E]
Cc: (b) (4), (b) (6); (b) (4), (b) (6);Adam, Stacey (FNIH) [T];Melencio, Cheryl (FNIH) [T]
Subject: Re: Partnership for Accelerating Cancer Therapies

That's terrific, and thanks Mark. We will work to set up a time that works for your team, David
Sent from my BlackBerry 10 smartphone.

From: (b) (4), (b);
Sent: Wednesday, June 28, 2017 5:57 PM
To: Collins, Francis (NIH/OD) [E]
Cc: Wholley, David (FNIH) [T]; (b) (4), (b) (6); (b) (4), (b) (6)
Subject: RE: Partnership for Accelerating Cancer Therapies

Great – we will move quickly and I am excited about how we are thinking about PACT.

Just finished watching your commencement address at SMU in May – loved it!

Mark

From: Collins, Francis (NIH/OD) [E] (b) (6)
Sent: Wednesday, June 28, 2017 5:51 PM
To: (b) (4), (b) (6)
Cc: Wholley, David (FNIH) [T] <dwholley@fnih.org>; (b) (4), (b) (6) >; (b) (4), (b) (6)
Subject: RE: Partnership for Accelerating Cancer Therapies

That sounds great, (b) (4). David will be happy to engage with your team after July 4.

Best, Francis

From: (b) (4), (b) (6)
Sent: Wednesday, June 28, 2017 5:47 PM
To: Collins, Francis (NIH/OD) [E] (b) (6)
Cc: Wholley, David (FNIH) [T] <dwholley@fnih.org>; (b) (4), (b) (6) (b) (4), (b) (6)
Subject: RE: Partnership for Accelerating Cancer Therapies

Hi Francis,

Thanks for your message and update on the commitment level required to participate.

First, we apologize for not responding back sooner. I'm happy to tell you that I met with key members of my team today and we are now very interested in joining this noble effort.

If acceptable to you and David, we would like to arrange a call for a time shortly after the July 4th holiday to ask a few questions before deciding on next steps.

All the best,

(b) (4),

From: Collins, Francis (NIH/OD) [E] (b) (6)]
Sent: Tuesday, June 27, 2017 3:39 PM
To: (b) (4), (b) (6)
Cc: Wholley, David (FNIH) [T] <dwholley@fnih.org>
Subject: Re: Partnership for Accelerating Cancer Therapies

Hi (b) (4),

I'm following up my message from May 6 (copied below) to see whether (b) (4) is interested in taking part in PACT. Since that message, I am glad to report that we have found ways to reduce the needed commitment per company to (b) (4), while sustaining the most critical part of the research plan. I am also happy to tell you that the White House has taken a strong interest in this project and is considering convening the group of participating companies for a significant Presidential event in July.

It would be terrific to have (b) (4) as a partner in this unprecedented effort. David Wholley of the Foundation for NIH (cc'd here) stands ready to answer any questions you might have about the current plan. Please let me know your thoughts.

Best, Francis

From: Collins, Francis (NIH/OD) [E]
Sent: Saturday, May 06, 2017 7:13 AM
To: (b) (4), (b) (6)
Cc: Wholley, David (FNIH) [T] <dwholley@fnih.org>
Subject: Partnership for Accelerating Cancer Therapies

Dear Mark:

It was a pleasure to meet you at the Milken LA meeting, and I'm glad we got a chance to talk about the Partnership for Accelerating Cancer Therapies (PACT), which we have been developing with multiple pharmaceutical companies and FDA over the last eight months or so. As we discussed, PACT is focused on the critical issue of developing better biomarkers for selecting and testing cancer immunotherapies and relevant combinations. Following up your request for more information, I have attached a text executive summary and a slide deck overviewing the partnership, as well as the full text of the white paper that contains the initial research plan for those who may need more detail.

(b) (4)

(b) (4)

All the best, Francis

****
THIS ELECTRONIC MAIL MESSAGE AND ANY ATTACHMENT IS CONFIDENTIAL AND MAY CONTAIN LEGALLY PRIVILEGED INFORMATION INTENDED ONLY FOR THE USE OF THE INDIVIDUAL OR INDIVIDUALS NAMED ABOVE.
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From: Wholley, David (FNIH) [T]
Sent: Mon, 9 Oct 2017 03:00:36 +0000
To: Harper, Sean;Collins, Francis (NIH/OD) [E]
Cc: Baker, Rebecca (NIH/OD) [E];Reese, David
Subject: Re: Partnership to Accelerate Cancer Therapies (PACT)

Hi David, is there a good time for me to call you tomorrow?
Sent from my BlackBerry 10 smartphone.

From: (b) (4), (b) (6)
Sent: Sunday, October 8, 2017 6:10 PM
To: Collins, Francis (NIH/OD) [E]
Cc: Wholley, David (FNIH) [T]; Baker, Rebecca (NIH/OD) [E]; (b) (4), (b) (6)
Subject: Re: Partnership to Accelerate Cancer Therapies (PACT)

Dear Francis,

(b) (4)

On Oct 2, 2017, at 2:38 PM, Collins, Francis (NIH/OD) [E] (b) (6) wrote:

Dear (b) (4),

I wanted to give you an update on the Partnership to Accelerate Cancer Therapies (PACT). As you may recall NIH worked with FNIH, FDA, and 14 pharmaceutical companies (b) (4) earlier this year to plan a public-private partnership that would help coordinate the development of standardized biomarkers and assays needed to conduct trials of new cancer immunotherapies and combination therapies. The resulting plan builds on a $160 million investment by NCI over 5 years in core laboratory and database infrastructure with (b) (4) to expand the number of novel markers, assays, and types of data that can be developed.

(b) (4)

(b) (4) As a result, we now have eight companies pledged to support PACT, and will be holding an announcement at the National Press Club here in Washington on October 12 with all of the participants.

(b) (4)

(b) (4) Might you be willing to reconsider joining PACT, given where things now stand? It would be great to know before Oct. 12th so we can include you in the planning for the announcement.

(b) (4)

Warm regards, Francis

<Updated PACT Executive Summary 092617.docx>

From: Wholley, David (FNIH) [T]
Sent: Wed, 13 Dec 2017 00:59:37 +0000
To: Biarnes, Michael (FNIH) [T];Collins, Francis (NIH/OD) [E];Koroshetz, Walter (NIH/NINDS) [E];Volkow, Nora (NIH/NIDA) [E];Stein, Jack (NIH/NIDA) [E];cflores2@its.jnj.com;osman.cigeroglu@pfizer.com;jdunlop@amgen.com;Oshinsky, Michael (NIH/NINDS) [E];Austin, Christopher (NIH/NCATS) [E];Colvis, Christine (NIH/NCATS) [E]
Cc: Baker, Rebecca (NIH/OD) [E];Menetski, Joseph (FNIH) [T]
Subject: Re: Partnership to Address the Opioids Crisis - Day 1 Summary

PS, we know the slides representing Nora's and Chris F.'s summations may repeat some earlier points but wanted to remind you what they felt were the key priorities. Hopefully we did not miss anything major.
Sent from my BlackBerry 10 smartphone.

From: Biarnes, Michael (FNIH) [T]
Sent: Tuesday, December 12, 2017 7:42 PM
To: Collins, Francis (NIH/OD) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Volkow, Nora (NIH/NIDA) [E]; Stein, Jack (NIH/NIDA) [E]; cflores2@its.jnj.com; osman.cigeroglu@pfizer.com; jdunlop@amgen.com; Oshinsky, Michael (NIH/NINDS) [E]; Austin, Christopher (NIH/NCATS) [E]; Colvis, Christine (NIH/NCATS) [E]
Cc: Baker, Rebecca (NIH/OD) [E]; Wholley, David (FNIH) [T]; Menetski, Joseph (FNIH) [T]
Subject: Partnership to Address the Opioids Crisis - Day 1 Summary

Dear all,

Please find the key decisions and action items that we noted from today's call attached for your review. The plan is for these to be reviewed by Drs. Collins and Flores with the group during the Meeting Summary to end tomorow. Please let us know if any edits are needed.

Thanks,
Mike

We've moved! Please find our new address below.
Michael Biarnes
Scientific Project Manager
Foundation for the National Institutes of Health
(301) 594-2612
fnih.org
11400 Rockville Pike Suite 600 North Bethesda, MD 20852

The FNIH is the #1 ranked biomedical research charitable organization & earned a 4-star rating from Charity Navigator.

From: Wholley, David (FNIH) [T]
Sent: Wed, 13 Dec 2017 12:18:28 +0000
To: Stein, Jack (NIH/NIDA) [E];Baker, Rebecca (NIH/OD) [E];Collins, Francis (NIH/OD) [E];Koroshetz, Walter (NIH/NINDS) [E];Volkow, Nora (NIH/NIDA) [E];Biarnes, Michael (FNIH) [T];cflores2@its.jnj.com;osman.cigeroglu@pfizer.com;jdunlop@amgen.com;Oshinsky, Michael (NIH/NINDS) [E];Austin, Christopher (NIH/NCATS) [E];Colvis, Christine (NIH/NCATS) [E]
Cc: Menetski, Joseph (FNIH) [T]
Subject: Re: Partnership to Address the Opioids Crisis - Day 1 Summary

Agree: remove opiant and titan, add pursuing endpoints with FDA via Patient Focused Drug Devt program to the bullet regarding endpoints. Link to ACTTION can go in white paper later.
Sent from my BlackBerry 10 smartphone.

From: Stein, Jack (NIH/NIDA) [E]
Sent: Wednesday, December 13, 2017 7:08 AM
To: Baker, Rebecca (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Volkow, Nora (NIH/NIDA) [E]; Biarnes, Michael (FNIH) [T]; cflores2@its.jnj.com; osman.cigeroglu@pfizer.com; jdunlop@amgen.com; Oshinsky, Michael (NIH/NINDS) [E]; Austin, Christopher (NIH/NCATS) [E]; Colvis, Christine (NIH/NCATS) [E]
Cc: Wholley, David (FNIH) [T]; Menetski, Joseph (FNIH) [T]
Subject: RE: Partnership to Address the Opioids Crisis - Day 1 Summary

Summary indeed looking good!
3 thinks to consider :
1. Did we really want to highlight Opiant and Titan in first slide ? - only companies mentioned in report out so might be misinterpreted (?)
2. The voice of the patient and family is an impt theme especially in endpoints so may want to be noted even if just verbally.
3. Here is link to the FDA supported ACTTION PPP which appears to be doing quite a lot re endpoints and other related items :http://www.acttion.org/consortia_collaborations

Jack
Sent with BlackBerry Work
(www.blackberry.com)

From: Baker, Rebecca (NIH/OD) [E] (b) (6)
Date: Wednesday, Dec 13, 2017, 6:35 AM
To: Collins, Francis (NIH/OD) [E] (b) (6), Koroshetz, Walter (NIH/NINDS) [E] (b) (6), Volkow, Nora (NIH/NIDA) [E] (b) (6), Biarnes, Michael (FNIH) [T] <mbiarnes@fnih.org>, Stein, Jack (NIH/NIDA) [E] (b) (6) cflores2@its.jnj.com <cflores2@its.jnj.com>, osman.cigeroglu@pfizer.com <osman.cigeroglu@pfizer.com>, jdunlop@amgen.com <jdunlop@amgen.com>, Oshinsky, Michael (NIH/NINDS) [E] (b) (6)>, Austin, Christopher (NIH/NCATS) [E] (b) (6), Colvis, Christine (NIH/NCATS) [E] (b) (6)
Cc: Wholley, David (FNIH) [T] <dwholley@fnih.org>, Menetski, Joseph (FNIH) [T] <jmenetski@fnih.org>
Subject: RE: Partnership to Address the Opioids Crisis - Day 1 Summary

Francis,

Please find a slightly revised version attached.

Thanks,
Rebecca

From: Collins, Francis (NIH/OD) [E]
Sent: Tuesday, December 12, 2017 8:47 PM
To: Koroshetz, Walter (NIH/NINDS) [E] (b) (6); Volkow, Nora (NIH/NIDA) [E] (b) (6); Biarnes, Michael (FNIH) [T] <mbiarnes@fnih.org>; Stein, Jack (NIH/NIDA) [E] (b) (6); cflores2@its.jnj.com; osman.cigeroglu@pfizer.com; jdunlop@amgen.com; Oshinsky, Michael (NIH/NINDS) [E] (b) (6); Austin, Christopher (NIH/NCATS) [E] (b) (6); Colvis, Christine (NIH/NCATS) [E] (b) (6)
Cc: Baker, Rebecca (NIH/OD) [E] (b) (6) Wholley, David (FNIH) [T] <dwholley@fnih.org>; Menetski, Joseph (FNIH) [T] <jmenetski@fnih.org>
Subject: RE: Partnership to Address the Opioids Crisis - Day 1 Summary

Appreciate Michael's excellent draft, and the edits/comments from Walter and Nora. Others may also want to comment.

I'll hold off making any further suggestions until tomorrow AM.

FC

From: Koroshetz, Walter (NIH/NINDS) [E]
Sent: Tuesday, December 12, 2017 8:43 PM
To: Volkow, Nora (NIH/NIDA) [E] (b) (6); Biarnes, Michael (FNIH) [T] <mbiarnes@fnih.org>; Collins, Francis (NIH/OD) [E] (b) (6); Stein, Jack (NIH/NIDA) [E] (b) (6); cflores2@its.jnj.com; osman.cigeroglu@pfizer.com; jdunlop@amgen.com; Oshinsky, Michael (NIH/NINDS) [E] (b) (6) Austin, Christopher (NIH/NCATS) [E] (b) (6); Colvis, Christine (NIH/NCATS) [E] (b) (6)
Cc: Baker, Rebecca (NIH/OD) [E] (b) (6); Wholley, David (FNIH) [T] <dwholley@fnih.org>; Menetski, Joseph (FNIH) [T] <jmenetski@fnih.org>
Subject: RE: Partnership to Address the Opioids Crisis - Day 1 Summary

Few edits on pain slides in red.
walter

From: Volkow, Nora (NIH/NIDA) [E]
Sent: Tuesday, December 12, 2017 8:40 PM
To: Biarnes, Michael (FNIH) [T] <mbiarnes@fnih.org>; Collins, Francis (NIH/OD) [E] (b) (6) Koroshetz, Walter (NIH/NINDS) [E] (b) (6); Stein, Jack (NIH/NIDA) [E] (b) (6); cflores2@its.jnj.com; osman.cigeroglu@pfizer.com; jdunlop@amgen.com; Oshinsky, Michael (NIH/NINDS) [E] (b) (6) Austin, Christopher (NIH/NCATS) [E] (b) (6); Colvis, Christine (NIH/NCATS) [E] (b) (6)
Cc: Baker, Rebecca (NIH/OD) [E] (b) (6); Wholley, David (FNIH) [T]

<dwholley@fnih.org>; Menetski, Joseph (FNIH) [T] <jmenetski@fnih.org>
Subject: Re: Partnership to Address the Opioids Crisis - Day 1 Summary

Michael I did some editing the OUD slides nora

From: "Biarnes, Michael (FNIH) [T]" <mbiarnes@fnih.org>
Date: Tuesday, December 12, 2017 at 7:42 PM
To: Francis Collins (b) (6)>, Walter Koroshetz (b) (6), Nora Volkow (b) (6)>, Jack Stein (b) (6) "cflores2@its.jnj.com" <cflores2@its.jnj.com>, "osman.cigeroglu@pfizer.com" <osman.cigeroglu@pfizer.com>, "jdunlop@amgen.com" <jdunlop@amgen.com>, "Oshinsky, Michael (NIH/NINDS) [E]" (b) (6), "Austin, Christopher (NIH/NCATS) [E]" (b) (6), "Colvis, Christine (NIH/NCATS) [E]" (b) (6)
Cc: "Baker, Rebecca (NIH/OD) [E]" (b) (6), "Wholley, David (FNIH) [T]" <dwholley@fnih.org>, "Menetski, Joseph (FNIH) [T]" <jmenetski@fnih.org>
Subject: Partnership to Address the Opioids Crisis - Day 1 Summary

Dear all,

Please find the key decisions and action items that we noted from today's call attached for your review. The plan is for these to be reviewed by Drs. Collins and Flores with the group during the Meeting Summary to end tomorow. Please let us know if any edits are needed.

Thanks,
Mike

We've moved! Please find our new address below.
Michael Biarnes
Scientific Project Manager
Foundation for the National Institutes of Health
(301) 594-2612
fnih.org
11400 Rockville Pike Suite 600 North Bethesda, MD 20852

The FNIH is the #1 ranked biomedical research charitable organization & earned a 4-star rating from Charity Navigator.

From: Wholley, David (FNIH) [T]
Sent: Wed, 6 Dec 2017 01:12:42 +0000
To: Collins, Francis (NIH/OD) [E];Biarnes, Michael (FNIH) [T]
Cc: Baker, Rebecca (NIH/OD) [E];Menetski, Joseph (FNIH) [T]
Subject: RE: Partnership to Address the Opioids Crisis Focus Area B Co-Chair Call

Francis, Mike just reminded me that this conflicts with your regularly scheduled update meeting (sorry but lots and lots of calls lately as you know). We apologize for the scheduling conflict, but this was absolutely the only time we could make this call work for a majority of the co-chairs even with weeks of notice, and I know it too is a call you specifically suggested.

From: Collins, Francis (NIH/OD) [E]
Sent: Tuesday, December 5, 2017 7:36 PM
To: Biarnes, Michael (FNIH) [T] <mbiarnes@fnih.org>
Cc: Baker, Rebecca (NIH/OD) [E] (b) (6); Wholley, David (FNIH) [T] <dwholley@fnih.org>; Menetski, Joseph (FNIH) [T] <jmenetski@fnih.org>
Subject: Re: Partnership to Address the Opioids Crisis Focus Area B Co-Chair Call

Thanks for the heads up!

Sent from my iPhone

On Dec 5, 2017, at 4:56 PM, Biarnes, Michael (FNIH) [T] <mbiarnes@fnih.org> wrote:

Dear Francis,

On Thursday we will be holding a meeting with the Focus Area B working group co-chairs from 12-2pm ET to discuss the progress of the working groups to date, structure of the face-to-face meeting, outline of the working group slides, and materials needed ahead of the face-to-face meeting. While we will necessarily be focused on preparing the pain effort for next week's face to face meeting, we have also invited Nora and Jack to join the call as it may be helpful to insure cohesion between the two Focus Areas. We just wanted you to know about the call in case it was not on your calendar and you wanted to join in for any reason.

Best,
Mike

We've moved! Please find our new address below.
Michael Biarnes
Scientific Project Manager
Foundation for the National Institutes of Health
(301) 594-2612
fnih.org
11400 Rockville Pike Suite 600 North Bethesda, MD 20852

The FNIH is the #1 ranked biomedical research charitable organization & earned a 4-star rating from Charity Navigator.

From: Wholley, David (FNIH) [T]
Sent: Wed, 11 Oct 2017 16:15:22 +0000
To: Myles, Renate (NIH/OD) [E];Collins, Francis (NIH/OD) [E]
Cc: Baker, Rebecca (NIH/OD) [E];Burklow, John (NIH/OD) [E];Adam, Stacey (FNIH) [T];Meltzer, Abbey (FNIH) [T]
Subject: RE: PLEASE REVIEW FINAL RELEASE
Attachments: DRAFT_Release_PACT_10.6.17_ASPA Clearance V2dw.docx

Here are my changes (in blue). Our comms person has also looked at this.

David Wholley
Director, Research Partnerships
Foundation for the National Institutes of Health
(301) 594-6343
fnih.org

*Learn more about the FNIH in our **2016 Annual Report**: fnih.org/AnnualReport.*

From: Myles, Renate (NIH/OD) [E]
Sent: Wednesday, October 11, 2017 11:33 AM
To: Collins, Francis (NIH/OD) [E] (b) (6); Wholley, David (FNIH) [T] <dwholley@fnih.org>
Cc: Baker, Rebecca (NIH/OD) [E] (b) (6); Burklow, John (NIH/OD) [E] (b) (6); Adam, Stacey (FNIH) [T] <sadam@fnih.org>
Subject: PLEASE REVIEW FINAL RELEASE
Importance: High

Hi Francis and David:

Attached is the final release that is marked up with company input. I'm still waiting for Hargan's quote, but would you confirm that the numbers are accurate? We plan to reproduce these for the press packs this afternoon.

Thanks,
Renate

(b) (5)

(b) (5)

(b) (5)

From: Wholley, David (FNIH) [T]
Sent: Wed, 11 Oct 2017 18:08:52 +0000
To: Collins, Francis (NIH/OD) [E];Myles, Renate (NIH/OD) [E]
Cc: Baker, Rebecca (NIH/OD) [E];Burklow, John (NIH/OD) [E];Adam, Stacey (FNIH) [T];Meltzer, Abbey (FNIH) [T]
Subject: RE: PLEASE REVIEW FINAL RELEASE

(b) (4), (b) (5)

(b) (4), (b) (5) David

David Wholley
Director, Research Partnerships
Foundation for the National Institutes of Health
(301) 594-6343
fnih.org

*Learn more about the FNIH in our **2016 Annual Report**: fnih.org/AnnualReport.*

From: Collins, Francis (NIH/OD) [E]
Sent: Wednesday, October 11, 2017 1:33 PM
To: Myles, Renate (NIH/OD) [E] (b) (6)
Cc: Baker, Rebecca (NIH/OD) [E] (b) (6); Wholley, David (FNIH) [T] <dwholley@fnih.org>; Burklow, John (NIH/OD) [E] (b) (6); Adam, Stacey (FNIH) [T] <sadam@fnih.org>; Meltzer, Abbey (FNIH) [T] <ameltzer@fnih.org>
Subject: RE: PLEASE REVIEW FINAL RELEASE

(b) (4), (b) (5)

FC

From: Wholley, David (FNIH) [T]
Sent: Wednesday, October 11, 2017 12:15 PM
To: Myles, Renate (NIH/OD) [E] (b) (6); Collins, Francis (NIH/OD) [E] (b) (6)
Cc: Baker, Rebecca (NIH/OD) [E] (b) (6) Burklow, John (NIH/OD) [E] (b) (6); Adam, Stacey (FNIH) [T] <sadam@fnih.org>; Meltzer, Abbey (FNIH) [T] <ameltzer@fnih.org>
Subject: RE: PLEASE REVIEW FINAL RELEASE

Here are my changes (in blue). Our comms person has also looked at this.

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From: Myles, Renate (NIH/OD) [E]
Sent: Wednesday, October 11, 2017 11:33 AM
To: Collins, Francis (NIH/OD) [E] (b) (6); Wholley, David (FNIH) [T] <dwholley@fnih.org>
Cc: Baker, Rebecca (NIH/OD) [E] (b) (6); Burklow, John (NIH/OD) [E] (b) (6); Adam, Stacey (FNIH) [T] <sadam@fnih.org>
Subject: PLEASE REVIEW FINAL RELEASE
Importance: High

Hi Francis and David:

Attached is the final release that is marked up with company input. I'm still waiting for Hargan's quote, but would you confirm that the numbers are accurate? We plan to reproduce these for the press packs this afternoon.

Thanks,
Renate

From: Wholley, David (FNIH) [T]
Sent: Fri, 30 Jun 2017 12:52:21 -0400
To: Collins, Francis (NIH/OD) [E];Tabak, Lawrence (NIH/OD) [E];Baker, Rebecca (NIH/OD) [E];Wolinetz, Carrie (NIH/OD) [E];Lowy, Douglas (NIH/NCI) [E];Doroshow, James (NIH/NCI) [E];Burklow, John (NIH/OD) [E]
Subject: RE: Possible PACT event at the White House

Hi Francis,

Here is the status:

(b) (4)

David Wholley
Director, Research Partnerships
Foundation for the National Institutes of Health
(301) 594-6343
fnih.org

*Learn more about the FNIH in our **2016 Annual Report**: fnih.org/AnnualReport.*

From: Collins, Francis (NIH/OD) [E]
Sent: Friday, June 30, 2017 12:18 PM
To: Wholley, David (FNIH) [T] <dwholley@fnih.org>; Tabak, Lawrence (NIH/OD) [E] (b) (6); Baker, Rebecca (NIH/OD) [E] (b) (6); Wolinetz, Carrie (NIH/OD) [E] (b) (6)>; Lowy, Douglas (NIH/NCI) [E] (b) (6) Doroshow, James (NIH/NCI) [E] (b) (6); Burklow, John (NIH/OD) [E] (b) (6)
Subject: Possible PACT event at the White House

Hi all,

I just spoke with Reed Cordish at the White House. We have a "tentative green light" for a White House event (including the POTUS) to announce the formation of PACT.

The event would include patients who have benefitted from cancer immunotherapy, cancer advocates, NCI/NIH, and the CEOs (or heads of R&D) of companies that have agreed to join. From the White House

perspective, it will be essential to have as many companies as possible. If there were less than five, this might be a No Go.

Reed would like to see the list of companies who are considering participation, and the state of their current commitment. David, can you provide me with that? No need to include details, just name of company and level of current interest.

They are looking at specific dates in the third or fourth week of July.

Assuming a critical mass of companies can be reached, Reed expects to give us a "100% go ahead" on Monday.

Francis

From: Wholley, David (FNIH) [T]
Sent: Wed, 6 Dec 2017 17:28:44 +0000
To: Collins, Francis (NIH/OD) [E];Tabak, Lawrence (NIH/OD) [E];Volkow, Nora (NIH/NIDA) [E];Stein, Jack (NIH/NIDA) [E];Koroshetz, Walter (NIH/NINDS) [E];Porter, Linda (NIH/NINDS) [E];Wolinetz, Carrie (NIH/OD) [E];Baker, Rebecca (NIH/OD) [E]
Subject: RE: Proposed agenda for Opioids Partnership F2F next week

Mike is revising the agenda accordingly. We'll insert Bill (or Rich) right after you, within a common block of time.

From: Collins, Francis (NIH/OD) [E]
Sent: Wednesday, December 6, 2017 12:13 PM
To: Wholley, David (FNIH) [T] <dwholley@fnih.org>; Tabak, Lawrence (NIH/OD) [E] (b) (6); Volkow, Nora (NIH/NIDA) [E] (b) (6); Stein, Jack (NIH/NIDA) [E] (b) (6); Koroshetz, Walter (NIH/NINDS) [E] (b) (6) Porter, Linda (NIH/NINDS) [E] (b) (6); Wolinetz, Carrie (NIH/OD) [E] (b) (6) Baker, Rebecca (NIH/OD) [E] (b) (6)
Subject: RE: Proposed agenda for Opioids Partnership F2F next week

To the extent possible, it would be good to maintain a similar structure for the meeting sessions on Focus A and B.

And I'm fine with a brief welcome from PhRMA.

FC

From: Wholley, David (FNIH) [T]
Sent: Tuesday, December 05, 2017 8:19 PM
To: Collins, Francis (NIH/OD) [E] (b) (6); Tabak, Lawrence (NIH/OD) [E] (b) (6); Volkow, Nora (NIH/NIDA) [E] (b) (6); Stein, Jack (NIH/NIDA) [E] (b) (6); Koroshetz, Walter (NIH/NINDS) [E] (b) (6) Porter, Linda (NIH/NINDS) [E] (b) (6) Wolinetz, Carrie (NIH/OD) [E] (b) (6); Baker, Rebecca (NIH/OD) [E] (b) (6)
Subject: FW: Proposed agenda for Opioids Partnership F2F next week

Thoughts? Happy to make changes. By the way, I don't think our budgeting segment is going to address actual estimates at this point—too early in most cases—but will rather discuss strategies for coming to such general estimations in the white paper writing process.

From: Chin, Bill [mailto:Chin@phrma.org]
Sent: Tuesday, December 5, 2017 5:47 PM
To: Wholley, David (FNIH) [T] (b) (6)
Cc: Baker, Rebecca (NIH/OD) [E] (b) (6); Biarnes, Michael (FNIH) [T] <mbiarnes@fnih.org>; Menetski, Joseph (FNIH) [T] <jmenetski@fnih.org>; Moscicki, Richard <rmoscicki@phrma.org>
Subject: RE: Proposed agenda for Opioids Partnership F2F next week

David, Two thoughts. First, on 12/13 you have scheduled a session entitled, "Focus Area B: Refinement and Budgeting." But there is not analogous session for Focus Area A. Second, I think you should let PhRMA join Francis in the Introduction to ensure the optics reflect the PPP. You don't even need to list either me or Rich but one of us should welcome everyone and particularly get a chance to thank the industry members for their participation. My two cents. Bill

---

From: Wholley, David (FNIH) [T] [mailto:dwholley@fnih.org]
Sent: Tuesday, December 05, 2017 1:31 PM
To: Chin, Bill
Cc: Baker, Rebecca (NIH/OD) [E]; Biarnes, Michael (FNIH) [T]; Menetski, Joseph (FNIH) [T]
Subject: Proposed agenda for Opioids Partnership F2F next week

Bill, please see the attached, result of our conversations with the NIH group so far, but pending input from the co-chairs and finalization. Please let me know if anything looks amiss.
David

We've moved! Please find our new address below.
David Wholley
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11400 Rockville Pike Suite 600 North Bethesda, MD 20852
*Learn more about the FNIH in our **2016 Annual Report**: fnih.org/AnnualReport.*

From: Wholley, David (FNIH) [T]
Sent: Fri, 10 Nov 2017 17:08:11 +0000
To: Baker, Rebecca (NIH/OD) [E]
Cc: Collins, Francis (NIH/OD) [E];Biarnes, Michael (FNIH) [T]
Subject: RE: quick review of draft note reserving 12-13 Dec

I have a concern with the 12-13 date, Rebecca. I am trying to determine if the room available—the only one we are able to find—will be big enough to accommodate all the people now on the list to come, and if not what a tenable solution would be around that time. I understand you are anxious to get this out, but I would ask that you please hold off until we are further confirmed on this.

From: Baker, Rebecca (NIH/OD) [E]
Sent: Friday, November 10, 2017 11:40 AM
To: Biarnes, Michael (FNIH) [T] <mbiarnes@fnih.org>; Wholley, David (FNIH) [T] <dwholley@fnih.org>
Subject: quick review of draft note reserving 12-13 Dec

Hi David and Michael,

Francis would like to send out today the note we discussed at yesterday's meeting, identifying the priority areas and informing the potential partners of the 12-13 date. Do you have any concerns with the attached draft?

Thanks for letting me know ASAP.

Best,
Rebecca

From: Wholley, David (FNIH) [T]
Sent: Fri, 27 Jan 2017 08:47:04 -0500
To: Collins, Francis (NIH/OD) [E];Katz, Stephen I. (NIH/NIAMS) [E]
Cc: Carter, Robert (NIH/NIAMS) [E]
Subject: Re: RA/lupus AMP

Yes, was just waiting for Steve to give you the good news. All three AMP initiatives are now officially a "go"!
Sent from my BlackBerry 10 smartphone.

From: Collins, Francis (NIH/OD) [E]
Sent: Friday, January 27, 2017 4:52 AM
To: Katz, Stephen I. (NIH/NIAMS) [E]
Cc: Wholley, David (FNIH) [T]; Carter, Robert (NIH/NIAMS) [E]
Subject: RE: RA/lupus AMP

Hi Steve,

This is great news – congratulations to all, especially Bob Carter. I'd be delighted to provide a video for the kickoff of Phase 2. And sometime soon I'd love to see a summary of the data from Phase 1.

It would be good to let the rest of the AMP Executive Committee know of this outcome – David, can you do that?

Best, Francis

From: Katz, Stephen I. (NIH/NIAMS) [E]
Sent: Thursday, January 26, 2017 6:05 PM
To: Collins, Francis (NIH/OD) [E] (b) (6)
Cc: Wholley, David (FNIH) [T] <dwholley@fnih.org>; Carter, Robert (NIH/NIAMS) [E]
(b) (6)
Subject: RA/lupus AMP

Hi Francis, the RA/lupus AMP Steering Committee just finished its call addressing the move from Phase 1 to Phase 2 of the program. The group (the 6 industry partners, the advocacy groups and the NIAID/NIAMS) all agreed to move ahead and invest in Phase 2. The investigators have been truly outstanding, with Michael Brenner's leadership, in working with the entire team in an open and very transparent way. The entire Steering Committee is meeting in Houston in the next 3 weeks to fine tune the next steps and goals of Phase 2.

A few things for you to know-
1-Bob Carter has been masterful in really shepherding this entire project. His co-chair is Marty Hodge from Pfizer who has also been critical in the endeavor moving forward.
2-Susana Sztein and her team at the NIAMS have been critical to the success by overseeing the project every step of the way.
3-The FNIH, led by Steve Hoffman, has done a masterful job in bringing us to the decision point and has also been critical to this entire endeavor. David Wholley has also been a very important leader in all of this.

Finally, Bob and I think that it might be a big boost to the group for you to record a short video for him to show at this second phase F2F meeting in Houston in a few weeks. He and our communications office will put something together if you agree.

Many thanks

Steve

Stephen I. Katz, MD, PHD
Director, NIAMS
National Institutes of Health
Bldg. 31 Rm. 4C32
Bethesda, MD 20892-2350
Phone: (b) (6)
Fax: (301) 402-3607
(b) (6)

National Institute of Arthritis and Musculoskeletal and Skin Diseases

NIH... Turning Discovery Into Health

From: Wholley, David (FNIH) [T]
Sent: Thu, 16 Mar 2017 12:39:20 -0400
To: Collins, Francis (NIH/OD) [E]
Subject: RE: Replacement for Francis Cuss on EC?

At variance with Jan's thoughts, but I agree either would be great. We'd just have to schedule our calls on European time.

From: Collins, Francis (NIH/OD) [E]
Sent: Thursday, March 16, 2017 10:52 AM
To: Wholley, David (FNIH) [T] <dwholley@fnih.org>
Subject: FW: Replacement for Francis Cuss on EC?

Either Stoffels or Vallance would be great. Your thoughts?

From: Dolsten, Mikael [mailto:Mikael.Dolsten@pfizer.com]
Sent: Thursday, March 16, 2017 8:44 AM
To: Collins, Francis (NIH/OD) [E] (b) (6)
Subject: Re: Replacement for Francis Cuss on EC?

I would suggest we start considering (b) (4), (b) (6) as they personally and their companies have shown a tradition to support global science/public health initiatives in US and EU
My ten cents ..
Mikael

Sent from my iPhone

On Mar 16, 2017, at 5:32 AM, Collins, Francis (NIH/OD) [E] (b) (6) wrote:

Dear Mikael,

In our very interesting and productive phone call earlier this week, I forgot to ask you an AMP question. As I'm sure you've heard, Francis Cuss has stepped down as CSO of BMS. In discussing this with David Wholley, we agree that we will need to elect a senior industry R&D executive to replace him on the AMP Executive Committee from among the companies not currently represented (AbbVie, Biogen, BMS, GSK, Janssen, Merck, Sanofi, Takeda), but also to have someone in mind that we think would be best suited to the role and be willing to give some time to it (although we've done a good job of trimming back our required meeting schedule). Do you have any thoughts about whom we should think about approaching? HEVER is coming up and it would be good to have some idea(s) before then.
Please let me know your thoughts. Happy to discuss by phone as well, involve others, etc. as you wish.

Regards, Francis

From: Wholley, David (FNIH) [T]
Sent: Thu, 6 Apr 2017 00:22:50 -0400
To: Collins, Francis (NIH/OD) [E];Doroshow, James (NIH/NCI) [E];Lowy, Douglas (NIH/NCI) [E]
Cc: Tabak, Lawrence (NIH/OD) [E];Baker, Rebecca (NIH/OD) [E];Schwetz, Tara (NIH/OD) [E];Adam, Stacey (FNIH) [T]
Subject: RE: Session 8 Hever 22 Cancer Moonshot_vF.pptx
Attachments: PACT Outreach Update 040517-FC.docx
Importance: High

Hi Francis:

No, like you we had not heard that there was going to be a "respondent" to your proposal (rather British of them…). But the fact that they have concerns is not unexpected, and we did hear about a few of these, which we were intending to include as part of your briefing materials due tomorrow but will try to answer here instead.

I had previously heard from Mikael Dolsten a suggestion that we might consider breaking PACT into 1-3 more tailored "sub-projects" that people could elect to join or not, much as was done with the different disease area proposals in AMP. I responded that we'd considered a number of different modular approaches to PACT, but the working groups had settled on defining a core investment around biomarkers and assays, plus limited investment in helping support specific trials of interest. (I said of course we'd be willing to hear his thoughts further on this, but got no response.) I called Axel Hoos about this, who said he'd heard something similar on a HEVER industry prep call that ended up being entirely about PACT, and which I imagine is where most of the concerns listed in the slides may have been raised. While it appears from the slides that the idea of reducing the overall investment has apparently persisted, at least the notion of having everyone pick a different favorite "project" seems to have been abandoned.

Axel is dead set against any kind of reduction in scope or budget and believes the whole program should be funded as proposed or it will fail. He is pushing that view with Patrick Vallance (though whether Patrick will stand up to support it at HEVER is hard to say). Nevertheless, I asked Stacey Adam how we might approach modularizing the $140M industry investment if it came to that. Our sense is that there are three modules, as follows, with approximate current estimated cost:

(b) (4), (b) (5)

Jim Doroshow and I also discussed the issue by phone last Thursday, and Jim told me he feels the new biomarker piece (2) is where the most value lies, but that this would be hard to realize without also investing substantially in the underlying infrastructure (1). (Please correct me if I am wrong here, Jim?) I

agree. Axel would not want to hear this but if there is one piece that could be cut it would likely be module 3, particularly the co-funding of trials, which could be done instead on a case by case basis if needed. As for further cuts in the first two modules: yes, you can always do fewer samples per year, or cut back on the types of assays you perform, or do "staged buy-in" of different biomarkers —though it is worth reminding the industry folks that their own people were very active in setting the initial list. At any rate, that kind of pruning is what the final Project Plan process is supposed to include.

I would like to hear Jim and Doug's view, but I think if there is a way we can keep the first two modules together, and without taking too much of a haircut, we should be able to execute on the vision laid out in the white paper to some degree. If on the other hand industry wants to only put $50M into this over five years, I would guess we are talking about a pretty different animal.

Other issues raised in the slides:

Other funding sources; could non-profits contribute? – as we have previously discussed, non-profits could contribute something—and we are active in asking them-- but outside of maybe Parker Foundation or Chan Zuckerberg Foundation I don't think the money would be significant; also, the big ones have their own research agendas to fund, and they will want to see a meaningful base investment from the industry partners first I think.

Flexible funding model—not sure what this means. The companies are the ones that originally said that every company should pay the same amount regardless of size, etc. Perhaps they are reconsidering this, which I would imagine is fine by all of us, though they'll probably need a rationale of some sort to sell the idea to each other.

Benefit of participating vs. accessing capabilities later. We've heard this from lots of people. There are a couple of ways to answer this. The first is the obvious truth that if not enough people invest and everybody waits they get none of what PACT is meant to provide (beyond the base investments by NIH of course). I think we also have discussed the ability to have an early look at data something akin to what we decided in AMP (which was up to 6 months while data is in QC) though we have been careful to say this will also be dependent on the restrictions inherent in the clinical trials. I also think what we are now seeing as the experience of the companies involved in the three AMP research initiatives is relevant: although the knowledge portals and data assets generated are made available broadly to the entire scientific community, the companies involved are best positioned to understand and use the data and tools generated by AMP. In many cases they are now working directly with the academic investigators who generated the data/tools on using them to figure out the best approaches to validate targets. Everyone else waits for publications to get these insights. We anticipate similar benefits from participation in PACT. Finally, companies who fund get to jointly participate with NIH and FDA in governance; while they cannot of course direct the use of federal funds, they have a clear say in how the industry funds are prioritized and directed. Companies that wait have no such say.

How do we make sure the biomarker effort is robust enough given that no diagnostic companies are involved? I think this is another way of expressing the distrust of having academic centers do biomarker development that we have already heard from several companies. A major benefit of having industry involved in PACT is to help insure we have the additional funds, expertise, and experience on board to make sure the right SOPs and standards are in place to make this happen. (Jim, I would guess you could add substantial detail to this answer.) You may also hear the suggestion we've heard from Novartis and a couple of other companies that some of the infrastructure funds be used to fund at least one

commercial lab partner (e.g., CRO). This can be done through FNIH if you want; up to you how you want to answer them. As for inclusion of dx companies, I suppose there is no reason we couldn't consider having them involved in PACT; they traditionally don't join these partnerships because of either financial limitations or because they have trouble viewing biomarker development as precompetitive the way pharma does. I think this might be able to be worked out, but would require more discussion.

Attached is the outreach grid we shared with you at our last meeting, updated to show the substantial activity since then, including meeting with or input from AZ, Bayer, B-I, Genentech, Pfizer, and Cancer Research Institute—most of it at AACR, and most of it positive. We are working on updating the additional detailed notes from these conversations and will send them to you and Jim tomorrow, along with some additional questions we've heard and how we answered them. Stacey and I are of course are happy to jump on the phone with any or all of you to discuss this further before HEVER.

Hope this is helpful.

David

From: Collins, Francis (NIH/OD) [E]
Sent: Wednesday, April 05, 2017 6:54 PM
To: Wholley, David (FNIH) [T] <dwholley@fnih.org>; Doroshow, James (NIH/NCI) [E] (b) (6); Lowy, Douglas (NIH/NCI) [E] (b) (6)
Cc: Tabak, Lawrence (NIH/OD) [E] (b) (6) Baker, Rebecca (NIH/OD) [E] (b) (6); Schwetz, Tara (NIH/OD) [E] (b) (6)
Subject: FW: Session 8 Hever 22 Cancer Moonshot_vF.pptx

Hi David, Jim, and Doug,

I didn't realize that our presentation on the Cancer Moonshot for Sunday morning was going to be followed by a respondent – but apparently so. See slides 24 – 27 in the attached set, and look especially at the last two.

Jim and I will need to be prepared to address those issues – especially regarding the absence of diagnostic companies in the PACT plan, and the suggestion that the industry contribution might have to be cut by 2 – 3x if the price is too high.

Reactions?

Francis

From: Sogaard, Morten [mailto:Morten.Sogaard@pfizer.com]
Sent: Wednesday, April 05, 2017 5:19 PM
To: Collins, Francis (NIH/OD) [E] (b) (6); Doroshow, James (NIH/NCI) [E] (b) (6)

Cc: Dolsten, Mikael <Mikael.Dolsten@pfizer.com>; Sogaard, Morten <Morten.Sogaard@pfizer.com>
Subject: Session 8 Hever 22 Cancer Moonshot_vF.pptx

Dear Francis, dear Jim,

Hoping that this e-mail finds both of you well, Mikael and I are very much looking forward to seeing you both on Sunday!

Thank you also for sharing your pre-read slides.
Please, find enclosed your slides followed by our discussion slides.

The session overall is an hour.
Our thought was to kick off with a brief intro by Mikael, followed by 15 minutes of overview by you, I will do 5 min summary of member input as well as discussion slide aimed at hopefully being able to driving significant progress during the meeting towards achieving broad buy-in. We then have a 30 minute discussion and wrap of decisions and actions towards the end.

Regarding the slides specifically, we wondered which of the slides you would plan to present during the meeting.
We have quite a few slides so just wanted to make sure we got enough time for discussion. Would it be helpful if you had 20 instead of 15 minutes?

Also, please let us know of any suggestions or comments regarding the event.

Mikael, please also pitch in with any comments etc.

Best regards,
Morten

Morten Sogaard, Ph.D. | Vice President and Head, WRD Genome Sciences & Technologies, Worldwide R&D |
Pfizer Inc 235 East 42nd Street, Office 235/6/40 | New York, NY 10017 | Phone: 212-733-2446 | Mobile (b) (6) |
morten.sogaard@pfizer.com Assistant: rosetta.giurdanella@pfizer.com | Phone: 212-573-1268

(b) (4)

(b) (4)

From: Wholley, David (FNIH) [T]
Sent: Fri, 6 Oct 2017 19:26:54 +0000
To: Collins, Francis (NIH/OD) [E];Baker, Rebecca (NIH/OD) [E];Wolinetz, Carrie (NIH/OD) [E];Tabak, Lawrence (NIH/OD) [E];Lowy, Douglas (NIH/NCI) [E];Doroshow, James (NIH/NCI) [E];Myles, Renate (NIH/OD) [E];Burklow, John (NIH/OD) [E]
Cc: Adam, Stacey (FNIH) [T]
Subject: Re: Speaking invitation: PACT press conference October 12

(b) (5)

Sent from my BlackBerry 10 smartphone.

From: Collins, Francis (NIH/OD) [E]
Sent: Friday, October 6, 2017 2:00 PM
To: Wholley, David (FNIH) [T]; Baker, Rebecca (NIH/OD) [E]; Wolinetz, Carrie (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Lowy, Douglas (NIH/NCI) [E]; Doroshow, James (NIH/NCI) [E]; Myles, Renate (NIH/OD) [E]; Burklow, John (NIH/OD) [E]
Subject: FW: Speaking invitation: PACT press conference October 12

(b) (5)

From: Sandra Horning [mailto:horning.sandra@gene.com]
Sent: Friday, October 06, 2017 1:56 PM
To: Collins, Francis (NIH/OD) [E] (b) (6)
Cc: Alanna Lyons <lyons.alanna@gene.com>; James Larkin <larkin.james@gene.com>
Subject: Re: Speaking invitation: PACT press conference October 12

Dear Francis,

I appreciate the honor of the invitation to participate in next week's PACT press conference but I have a long standing commitment with my team, some of whom are coming from Europe, that conflicts with that date.

I do hope you have a highly successful event and trust that among the multiple industry partners that you will readily identify a representative speaker.

All the best and thank you for your consideration,
Sandra

On Oct 6, 2017, at 9:39 AM, Collins, Francis (NIH/OD) [E] (b) (6) wrote:

Dear Sandra,

Many thanks to you and your colleagues at Genentech for your contributions to the design of PACT, and for agreeing to take the next step with us in this important and exciting partnership.

We are assembling the agenda for the event next week announcing the partnership, and would like to invite you to say a few words representing the 9 private sector partners in PACT (Novartis has also just joined). We would set aside approximately 5-7 minutes for your remarks, and would be pleased to assist you in any way as you prepared for the event. Other speakers will likely include the Acting HHS Secretary, myself, Acting NCI Director Douglas Lowy, and a patient who has benefitted from chemotherapy.

With apologies for the last minute request, please let me know at your earliest convenience whether you'd be interested in speaking next week.

Thank you again,

Francis

From: Collins, Francis (NIH/OD) [E]
Sent: Tuesday, October 3, 2017 9:29 PM
To: michael.severino@abbvie.com; thomas.hudson@abbvie.com; norbert.kraut@boehringer-ingelheim.com; thomas.lynch@bms.com; rvessey@celgene.com; horning.sandra@gene.com; perez.edith@gene.com; patrick.5.vallance@gsk.com; axel.x.hoos@gsk.com; Mikael.Dolsten@pfizer.com; paul.rejto@pfizer.com; robert.abraham@pfizer.com; PStoffe4@its.jnj.com; plebowit@its.jnj.com
Cc: Myles, Renate (NIH/OD) [E] (b) (6); Burklow, John (NIH/OD) [E] (b) (6); Baker, Rebecca (NIH/OD) [E] (b) (6)>; Wholley, David (FNIH) [T] <dwholley@fnih.org>; Tabak, Lawrence (NIH/OD) [E] (b) (6)>; Wolinetz, Carrie (NIH/OD) [E] (b) (6); Lowy, Douglas (NIH/NCI) [E] (b) (6) Doroshow, James (NIH/NCI) [E] (b) (6)
Subject: Invitation to PACT press conference October 12

Dear Colleagues:

We've been working together for more than a year to develop the Partnership to Accelerate Cancer Therapies (PACT) and I am excited to invite you to participate with HHS, NIH, NCI, FDA, and the Foundation for the NIH in a press conference at the National Press Club on Thursday, Oct. 12 at 10:00 a.m. ET to launch this important new partnership. The NPC is located at 528 14th St. NW, Washington, D.C. We have reserved a green room for the entire day (Zenger Room) and will hold a "pre-event" meeting in this room at 9:15 a.m., with the press conference beginning promptly at 10:00 a.m. ET in the Fourth Estate Room.

Given recent changes in HHS leadership, we are not quite sure who will serve as Departmental convener of the press conference, but it is likely to be Acting Secretary Don Wright. Following that, brief remarks will be made by myself, potentially NCI Director Ned Sharpless, whom we hope to have officially on

board by then, an industry representative, and a patient who has benefited from cancer immunotherapy. There is also a possibility that Reed Cordish, the White House Assistant to the President for Intragovernmental and Technology Initiatives, will join the event.

We hope to leave a good amount of time for questions from reporters. We will have the front rows reserved for speakers, members of the media, and yourselves. Also, after the event, reporters may want to speak with you, so I hope you can stay around for a bit after the formal meeting. Seating is limited, so please limit your organization's participation to yourself (or a surrogate) plus one.

We will likely have event itinerary and materials to share with you next week. Please provide to mylesr@mail.nih.gov the name and contact information for your communications director, so that John Burklow and Renate Myles on our NIH Communications staff can coordinate with them on materials and quotes to include in our media kits.

Best regards, and thanks for your support of this groundbreaking initiative,
Francis

From: Wholley, David (FNIH) [T]
Sent: Fri, 6 Oct 2017 20:28:49 +0000
To: Collins, Francis (NIH/OD) [E];Baker, Rebecca (NIH/OD) [E];Wolinetz, Carrie (NIH/OD) [E];Tabak, Lawrence (NIH/OD) [E];Lowy, Douglas (NIH/NCI) [E];Doroshow, James (NIH/NCI) [E];Myles, Renate (NIH/OD) [E];Burklow, John (NIH/OD) [E]
Cc: Adam, Stacey (FNIH) [T]
Subject: RE: Speaking invitation: PACT press conference October 12

(b) (5)

David Wholley
Director, Research Partnerships
Foundation for the National Institutes of Health
(301) 594-6343
fnih.org

*Learn more about the FNIH in our **2016 Annual Report**: fnih.org/AnnualReport.*

From: Collins, Francis (NIH/OD) [E]
Sent: Friday, October 06, 2017 4:24 PM
To: Wholley, David (FNIH) [T] <dwholley@fnih.org>; Baker, Rebecca (NIH/OD) [E] (b) (6); Wolinetz, Carrie (NIH/OD) [E] (b) (6)>; Tabak, Lawrence (NIH/OD) [E] (b) (6); Lowy, Douglas (NIH/NCI) [E] (b) (6); Doroshow, James (NIH/NCI) [E] (b) (6) Myles, Renate (NIH/OD) [E] (b) (6)>; Burklow, John (NIH/OD) [E] (b) (6)
Cc: Adam, Stacey (FNIH) [T] <sadam@fnih.org>
Subject: RE: Speaking invitation: PACT press conference October 12

(b) (5)

FC

From: Wholley, David (FNIH) [T]
Sent: Friday, October 06, 2017 3:27 PM
To: Collins, Francis (NIH/OD) [E] (b) (6)v>; Baker, Rebecca (NIH/OD) [E] (b) (6); Wolinetz, Carrie (NIH/OD) [E] (b) (6); Tabak, Lawrence (NIH/OD) [E] (b) (6)>; Lowy, Douglas (NIH/NCI) [E] (b) (6) Doroshow, James (NIH/NCI) [E] (b) (6)>; Myles, Renate (NIH/OD) [E] (b) (6)>; Burklow, John (NIH/OD) [E] (b) (6)
Cc: Adam, Stacey (FNIH) [T] <sadam@fnih.org>
Subject: Re: Speaking invitation: PACT press conference October 12

(b) (5)

Sent from my BlackBerry 10 smartphone.

From: Collins, Francis (NIH/OD) [E]
Sent: Friday, October 6, 2017 2:00 PM
To: Wholley, David (FNIH) [T]; Baker, Rebecca (NIH/OD) [E]; Wolinetz, Carrie (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Lowy, Douglas (NIH/NCI) [E]; Doroshow, James (NIH/NCI) [E]; Myles, Renate (NIH/OD) [E]; Burklow, John (NIH/OD) [E]
Subject: FW: Speaking invitation: PACT press conference October 12

(b) (5)

From: Sandra Horning [mailto:horning.sandra@gene.com]
Sent: Friday, October 06, 2017 1:56 PM
To: Collins, Francis (NIH/OD) [E] (b) (6)
Cc: Alanna Lyons <lyons.alanna@gene.com>; James Larkin <larkin.james@gene.com>
Subject: Re: Speaking invitation: PACT press conference October 12

Dear Francis,

I appreciate the honor of the invitation to participate in next week's PACT press conference but I have a long standing commitment with my team, some of whom are coming from Europe, that conflicts with that date.

I do hope you have a highly successful event and trust that among the multiple industry partners that you will readily identify a representative speaker.

All the best and thank you for your consideration,
Sandra

On Oct 6, 2017, at 9:39 AM, Collins, Francis (NIH/OD) [E] (b) (6) wrote:

Dear Sandra,

Many thanks to you and your colleagues at Genentech for your contributions to the design of PACT, and for agreeing to take the next step with us in this important and exciting partnership.

We are assembling the agenda for the event next week announcing the partnership, and would like to invite you to say a few words representing the 9 private sector partners in PACT (Novartis has also just joined). We would set aside approximately 5-7 minutes for your remarks, and would be pleased to assist

you in any way as you prepared for the event. Other speakers will likely include the Acting HHS Secretary, myself, Acting NCI Director Douglas Lowy, and a patient who has benefitted from chemotherapy.

With apologies for the last minute request, please let me know at your earliest convenience whether you'd be interested in speaking next week.

Thank you again,

Francis

From: Collins, Francis (NIH/OD) [E]
Sent: Tuesday, October 3, 2017 9:29 PM
To: michael.severino@abbvie.com; thomas.hudson@abbvie.com; norbert.kraut@boehringer-ingelheim.com; thomas.lynch@bms.com; rvessey@celgene.com; horning.sandra@gene.com; perez.edith@gene.com; patrick.5.vallance@gsk.com; axel.x.hoos@gsk.com; Mikael.Dolsten@pfizer.com; paul.rejto@pfizer.com; robert.abraham@pfizer.com; PStoffe4@its.jnj.com; plebowit@its.jnj.com
Cc: Myles, Renate (NIH/OD) [E] (b) (6) Burklow, John (NIH/OD) [E] (b) (6); Baker, Rebecca (NIH/OD) [E] (b) (6); Wholley, David (FNIH) [T] <dwholley@fnih.org>; Tabak, Lawrence (NIH/OD) [E] (b) (6); Wolinetz, Carrie (NIH/OD) [E] (b) (6); Lowy, Douglas (NIH/NCI) [E] (b) (6); Doroshow, James (NIH/NCI) [E] (b) (6)
Subject: Invitation to PACT press conference October 12

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We will likely have event itinerary and materials to share with you next week. Please provide to (b) (6) the name and contact information for your communications director, so that John Burklow and Renate Myles on our NIH Communications staff can coordinate with them on materials and quotes to include in our media kits.

Best regards, and thanks for your support of this groundbreaking initiative,
Francis

From: Wholley, David (FNIH) [T]
Sent: Thu, 21 Dec 2017 20:27:33 +0000
To: Moscicki, Richard
Subject: RE: Summary of the summit meeting

Rich, the only change I noticed was breaking out the AMP and PACT stuff into a separate section. I noticed that there is a typo in "Partnerships" in header for page 4, but otherwise it looks fine to me. Thanks, David

---

From: Moscicki, Richard [mailto:rmoscicki@phrma.org]
Sent: Thursday, December 21, 2017 2:36 PM
To: Wholley, David (FNIH) [T] <dwholley@fnih.org>
Subject: Summary of the summit meeting

Hi David, attached are some minor changes in the document. If you are ok with them, we will send to BMAC after legal review. Rich.

From: Wholley, David (FNIH) [T]
Sent: Sun, 28 Jan 2018 00:50:43 +0000
To: Baker, Rebecca (NIH/OD) [E]
Cc: Collins, Francis (NIH/OD) [E];Biarnes, Michael (FNIH) [T];Menetski, Joseph (FNIH) [T]
Subject: Opioid White Paper First Draft Master Jan 27
Attachments: Opioid White Paper First Draft Master Jan 27.docx
Importance: High

Rebecca, here is the first draft of the Opioids Partnership White Paper to take through NIH review. It contains everything except the Executive Summary, which we are working on in parallel (and essentially will just repeat what is in the document, compressed into two pages). We'll send that along separately when it is finished.

It's a big document, and final edits took us all day, so I apologize we were not able to get it out this morning.

Francis asked for an early look in our last NIH opioid team meeting, and given the lateness of the hour, I am copying him directly on this as well. Please send edits to me and Mike Biarnes and copy Joe Menetski at your earliest convenience. Rich M. has still asked for something on Feb. 1 so it can be sent to the CEOs in time for the Feb. 7 meeting. FYI I am sending this now also to the co-chairs, to FDA, and to PhRMA as we agreed, for their initial edits.

Thanks for your patience

David

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From: Wholley, David (FNIH) [T]
Sent: Fri, 19 Jan 2018 21:28:40 +0000
To: Collins, Francis (NIH/OD) [E];Baker, Rebecca (NIH/OD) [E]
Subject: Re: FDA involvement in the opioids partnership

Fingers crossed.
Sent from my BlackBerry 10 smartphone.

From: Collins, Francis (NIH/OD) [E]
Sent: Friday, January 19, 2018 3:29 PM
To: Wholley, David (FNIH) [T]; Baker, Rebecca (NIH/OD) [E]
Subject: RE: FDA involvement in the opioids partnership

Let me speak with him in Davos – assuming we both end up going....

From: Wholley, David (FNIH) [T]
Sent: Friday, January 19, 2018 3:26 PM
To: Collins, Francis (NIH/OD) [E] (b) (6); Baker, Rebecca (NIH/OD) [E]
(b) (6)
Subject: Fw: FDA involvement in the opioids partnership

Please see below. How do we convey this specifically to Scott?
Sent from my BlackBerry 10 smartphone.

From: Moscicki, Richard <rmoscicki@phrma.org>
Sent: Friday, January 19, 2018 3:02 PM
To: Wholley, David (FNIH) [T]
Subject: RE: FDA involvement in the opioids partnership

David, that is great news. If we can work out how to get that into the white paper it would go a long way. (b) (4)
(b) (4)
(b) (4) I think I could then very comfortably make the case to BMAC that they have been heard and this is going in the right direction. I think we can get by then without seeking legislative approaches, which I worry might be counterproductive.
While I have you, I am setting things up for the board meeting and our subcommittee that will review and endorse the partnership for a subsequent board vote. The key component I have to frame is the proposed cost for industry, ie the budget. Could I communicate with the chairs of the working groups to discuss the budgets? Rich.

From: Wholley, David (FNIH) [T] [mailto:dwholley@fnih.org]
Sent: Friday, January 19, 2018 2:36 PM
To: Moscicki, Richard <rmoscicki@phrma.org>
Cc: Collins, Francis (NIH/OD) [E] (b) (6); Baker, Rebecca (NIH/OD) [E]

(b) (6)

Subject: FDA involvement in the opioids partnership

Rich,
I had a chance to catch up with Francis and his team today and brought up the idea of a statement from FDA that could be incorporated into the white paper. It turns out that as part of Francis's conversation with Scott Gottlieb last week Scott promised to incorporate FDA's thoughts on supporting for new regulatory pathways for OUD and pain into an actual guidance that could then be referenced in the paper. He said this could be done relatively quickly, although not sure what that means in practice. Question for you is whether you think that will work to satisfy the interest you heard from the BMAC, or do we need to consider another course?

Thanks,
David

David Wholley
Director, Research Partnerships
Foundation for the National Institutes of Health
(301) 594-6343
fnih.org
11400 Rockville Pike Suite 600 North Bethesda, MD 20852

2017 Gold Stevie Award Winner for Organization of the Year

From: Wholley, David (FNIH) [T]
Sent: Sun, 7 Jan 2018 16:15:12 +0000
To: Volkow, Nora (NIH/NIDA) [E];Biarnes, Michael (FNIH) [T];Collins, Francis (NIH/OD) [E];Tabak, Lawrence (NIH/OD) [E];Wolinetz, Carrie (NIH/OD) [E];Koroshetz, Walter (NIH/NINDS) [E];Porter, Linda (NIH/NINDS) [E];Stein, Jack (NIH/NIDA) [E];Baker, Rebecca (NIH/OD) [E]
Cc: Menetski, Joseph (FNIH) [T]
Subject: RE: Meeting Materials: Thursday January 4 Opioid PPP Meeting
Attachments: 12+13Dec2017_Opioid PPP_F2F_Summary Draft Rev combined ndvdw.docx, 12+13Dec2017_Opioid PPP_F2F_Summary Draft Rev combined clean 1-7-18.docx
Importance: High

Thanks Nora, for your input, and to all for the very good comments and suggestions. I have made some changes in response to these and answered most of the comments in the attached draft this morning. Walter and Linda, we are only lacking your input to get this moving out to the meeting participants. Could you please give us your input? Given the number of changes I have included a clean version with the major changes accepted (comments remain for reference). Could you please make any additional changes to that and send back to Mike Biarnes as soon as possible, copying all per usual? Thanks, David

---

From: Volkow, Nora (NIH/NIDA) [E]
Sent: Saturday, January 6, 2018 12:52 PM
To: Biarnes, Michael (FNIH) [T] <mbiarnes@fnih.org>; Collins, Francis (NIH/OD) [E] (b) (6); Tabak, Lawrence (NIH/OD) [E] (b) (6); Wolinetz, Carrie (NIH/OD) [E] (b) (6); Koroshetz, Walter (NIH/NINDS) [E] (b) (6); Porter, Linda (NIH/NINDS) [E] (b) (6) Stein, Jack (NIH/NIDA) [E] (b) (6); Baker, Rebecca (NIH/OD) [E] (b) (6)
Cc: Wholley, David (FNIH) [T] <dwholley@fnih.org>; Menetski, Joseph (FNIH) [T] <jmenetski@fnih.org>; Volkow, Nora (NIH/NIDA) [E] (b) (6)
Subject: Re: Meeting Materials: Thursday January 4 Opioid PPP Meeting

Michael see my edit to the document using the document that Rebecca and jack edited nora

---

From: "Biarnes, Michael (FNIH) [T]" <mbiarnes@fnih.org>
Date: Friday, January 5, 2018 at 1:29 PM
To: Francis Collins (b) (6), "Tabak, Lawrence (NIH/OD) [E]" (b) (6)>, "Wolinetz, Carrie (NIH/OD) [E]" (b) (6)>, Walter Koroshetz (b) (6), Nora Volkow (b) (6)>, "Porter, Linda (NIH/NINDS) [E]" (b) (6), Jack Stein (b) (6), "Baker, Rebecca (NIH/OD) [E]" (b) (6)
Cc: "Wholley, David (FNIH) [T]" <dwholley@fnih.org>, "Menetski, Joseph (FNIH) [T]"

<jmenetski@fnih.org>
Subject: RE: Meeting Materials: Thursday January 4 Opioid PPP Meeting

Hi all,

As a reminder we aim to send these notes out to all meeting participants by COB today. Please provide any additional feedback by 5PM ET on top of Francis's comments (attached).

Thanks,
Mike

From: Collins, Francis (NIH/OD) [E]
Sent: Thursday, January 4, 2018 7:24 AM
To: Biarnes, Michael (FNIH) [T] <mbiarnes@fnih.org>; Tabak, Lawrence (NIH/OD) [E] (b) (6); Wolinetz, Carrie (NIH/OD) [E] (b) (6); Koroshetz, Walter (NIH/NINDS) [E] (b) (6); Volkow, Nora (NIH/NIDA) [E] (b) (6); Porter, Linda (NIH/NINDS) [E] (b) (6); Stein, Jack (NIH/NIDA) [E] (b) (6) Baker, Rebecca (NIH/OD) [E] (b) (6)
Cc: Wholley, David (FNIH) [T] <dwholley@fnih.org>; Menetski, Joseph (FNIH) [T] <jmenetski@fnih.org>
Subject: RE: Meeting Materials: Thursday January 4 Opioid PPP Meeting

See some suggested edits/comments on the meeting summary from December 12 – 13, which is generally very well done.

FC

From: Biarnes, Michael (FNIH) [T]
Sent: Wednesday, January 03, 2018 7:32 PM
To: Collins, Francis (NIH/OD) [E] (b) (6); Tabak, Lawrence (NIH/OD) [E] (b) (6); Wolinetz, Carrie (NIH/OD) [E] (b) (6); Koroshetz, Walter (NIH/NINDS) [E] (b) (6)>; Volkow, Nora (NIH/NIDA) [E] (b) (6); Porter, Linda (NIH/NINDS) [E] (b) (6); Stein, Jack (NIH/NIDA) [E] (b) (6); Baker, Rebecca (NIH/OD) [E] (b) (6)>
Cc: Wholley, David (FNIH) [T] <dwholley@fnih.org>; Menetski, Joseph (FNIH) [T] <jmenetski@fnih.org>
Subject: Meeting Materials: Thursday January 4 Opioid PPP Meeting

Good evening,

I hope that you all had a wonderful break. In preparation for tomorrow's meeting, please find the following attached:

1. A white paper outline with corresponding writing assignments for individual sections.
2. A more detailed summary of the face-to-face meeting held on Dec 12 + 13 for review – Goal is to send to all meeting attendees by Friday, January 5th.
3. An Excel file highlighting important dates and upcoming meetings for white paper development.

We have left a comment in the face-to-face meeting notes seeking input as to the level of detail to provide for a particular section so we do ask that you pay particular attention to that section. Otherwise, please redline the document with any revisions that you feel are needed to properly capture the meeting discussion by COB on Friday.

Best,
Mike

Michael Biarnes
Scientific Project Manager
Foundation for the National Institutes of Health
(301) 594-2612
fnih.org
11400 Rockville Pike Suite 600 North Bethesda, MD 20852

2017 Gold Stevie Award Winner for Organization of the Year

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From: Wholley, David (FNIH) [T]
Sent: Mon, 8 Jan 2018 12:54:57 +0000
To: Koroshetz, Walter (NIH/NINDS) [E];Volkow, Nora (NIH/NIDA) [E];Biarnes, Michael (FNIH) [T];Collins, Francis (NIH/OD) [E];Tabak, Lawrence (NIH/OD) [E];Wolinetz, Carrie (NIH/OD) [E];Porter, Linda (NIH/NINDS) [E];Stein, Jack (NIH/NIDA) [E];Baker, Rebecca (NIH/OD) [E]
Cc: Menetski, Joseph (FNIH) [T]
Subject: Re: Meeting Materials: Thursday January 4 Opioid PPP Meeting

Thanks, Walter!
Sent from my BlackBerry 10 smartphone.

From: Koroshetz, Walter (NIH/NINDS) [E]
Sent: Sunday, January 7, 2018 10:23 PM
To: Wholley, David (FNIH) [T]; Volkow, Nora (NIH/NIDA) [E]; Biarnes, Michael (FNIH) [T]; Collins, Francis (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Wolinetz, Carrie (NIH/OD) [E]; Porter, Linda (NIH/NINDS) [E]; Stein, Jack (NIH/NIDA) [E]; Baker, Rebecca (NIH/OD) [E]
Cc: Menetski, Joseph (FNIH) [T]
Subject: RE: Meeting Materials: Thursday January 4 Opioid PPP Meeting

Thanks David and Michael.
I included my suggestions for edits using *track change*.
walter

From: Wholley, David (FNIH) [T]
Sent: Sunday, January 07, 2018 11:15 AM
To: Volkow, Nora (NIH/NIDA) [E] (b) (6); Biarnes, Michael (FNIH) [T] <mbiarnes@fnih.org>; Collins, Francis (NIH/OD) [E] (b) (6); Tabak, Lawrence (NIH/OD) [E] (b) (6); Wolinetz, Carrie (NIH/OD) [E] (b) (6); Koroshetz, Walter (NIH/NINDS) [E] (b) (6); Porter, Linda (NIH/NINDS) [E] (b) (6); Stein, Jack (NIH/NIDA) [E] (b) (6) Baker, Rebecca (NIH/OD) [E] (b) (6)
Cc: Menetski, Joseph (FNIH) [T] <jmenetski@fnih.org>
Subject: RE: Meeting Materials: Thursday January 4 Opioid PPP Meeting
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To: Biarnes, Michael (FNIH) [T] <mbiarnes@fnih.org>; Collins, Francis (NIH/OD) [E] (b) (6); Tabak, Lawrence (NIH/OD) [E] (b) (6); Wolinetz, Carrie

(NIH/OD) [E] (b) (6); Koroshetz, Walter (NIH/NINDS) [E] (b) (6); Porter, Linda (NIH/NINDS) [E] (b) (6)>; Stein, Jack (NIH/NIDA) [E] (b) (6) Baker, Rebecca (NIH/OD) [E] (b) (6)
Cc: Wholley, David (FNIH) [T] <dwholley@fnih.org>; Menetski, Joseph (FNIH) [T] <jmenetski@fnih.org>; Volkow, Nora (NIH/NIDA) [E] (b) (6)
Subject: Re: Meeting Materials: Thursday January 4 Opioid PPP Meeting

Michael see my edit to the document using the document that Rebecca and jack edited nora

---

From: "Biarnes, Michael (FNIH) [T]" <mbiarnes@fnih.org>
Date: Friday, January 5, 2018 at 1:29 PM
To: Francis Collins (b) (6), "Tabak, Lawrence (NIH/OD) [E]" (b) (6)>, "Wolinetz, Carrie (NIH/OD) [E]" (b) (6), Walter Koroshetz (b) (6), Nora Volkow (b) (6), "Porter, Linda (NIH/NINDS) [E]" (b) (6)>, Jack Stein (b) (6), "Baker, Rebecca (NIH/OD) [E]" (b) (6)
Cc: "Wholley, David (FNIH) [T]" <dwholley@fnih.org>, "Menetski, Joseph (FNIH) [T]" <jmenetski@fnih.org>
Subject: RE: Meeting Materials: Thursday January 4 Opioid PPP Meeting

Hi all,

As a reminder we aim to send these notes out to all meeting participants by COB today. Please provide any additional feedback by 5PM ET on top of Francis's comments (attached).

Thanks,
Mike

From: Collins, Francis (NIH/OD) [E]
Sent: Thursday, January 4, 2018 7:24 AM
To: Biarnes, Michael (FNIH) [T] <mbiarnes@fnih.org>; Tabak, Lawrence (NIH/OD) [E] (b) (6); Wolinetz, Carrie (NIH/OD) [E] (b) (6); Koroshetz, Walter (NIH/NINDS) [E] (b) (6); Volkow, Nora (NIH/NIDA) [E] (b) (6); Porter, Linda (NIH/NINDS) [E] (b) (6); Stein, Jack (NIH/NIDA) [E] (b) (6) Baker, Rebecca (NIH/OD) [E] (b) (6)
Cc: Wholley, David (FNIH) [T] <dwholley@fnih.org>; Menetski, Joseph (FNIH) [T] <jmenetski@fnih.org>
Subject: RE: Meeting Materials: Thursday January 4 Opioid PPP Meeting

See some suggested edits/comments on the meeting summary from December 12 – 13, which is generally very well done.

FC

From: Biarnes, Michael (FNIH) [T]
Sent: Wednesday, January 03, 2018 7:32 PM
To: Collins, Francis (NIH/OD) [E] (b) (6) Tabak, Lawrence (NIH/OD) [E] (b) (6); Wolinetz, Carrie (NIH/OD) [E] (b) (6); Koroshetz, Walter (NIH/NINDS) [E] (b) (6); Volkow, Nora (NIH/NIDA) [E] (b) (6); Porter, Linda (NIH/NINDS) [E] (b) (6); Stein, Jack (NIH/NIDA) [E] (b) (6); Baker, Rebecca (NIH/OD) [E] (b) (6)
Cc: Wholley, David (FNIH) [T] <dwholley@fnih.org>; Menetski, Joseph (FNIH) [T] <jmenetski@fnih.org>
Subject: Meeting Materials: Thursday January 4 Opioid PPP Meeting

Good evening,

I hope that you all had a wonderful break. In preparation for tomorrow's meeting, please find the following attached:

1. A white paper outline with corresponding writing assignments for individual sections.
2. A more detailed summary of the face-to-face meeting held on Dec 12 + 13 for review – Goal is to send to all meeting attendees by Friday, January 5th.
3. An Excel file highlighting important dates and upcoming meetings for white paper development.

We have left a comment in the face-to-face meeting notes seeking input as to the level of detail to provide for a particular section so we do ask that you pay particular attention to that section. Otherwise, please redline the document with any revisions that you feel are needed to properly capture the meeting discussion by COB on Friday.

Best,
Mike

Michael Biarnes
Scientific Project Manager
Foundation for the National Institutes of Health
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fnih.org
11400 Rockville Pike Suite 600 North Bethesda, MD 20852

2017 Gold Stevie Award Winner for Organization of the Year

From: Wholley, David (FNIH) [T]
Sent: Tue, 30 Jan 2018 15:22:15 +0000
To: Myles, Renate (NIH/OD) [E];Collins, Francis (NIH/OD) [E];Tabak, Lawrence (NIH/OD) [E];Wolinetz, Carrie (NIH/OD) [E];Koroshetz, Walter (NIH/NINDS) [E];Freire, Maria (FNIH) [T];Hallett, Adrienne (NIH/OD) [E]
Cc: Burklow, John (NIH/OD) [E];Prince, Scott (NIH/OD) [E];Higgins, Lauren (NIH/OD) [E];Fine, Amanda (NIH/OD) [E];Wojtowicz, Emma (NIH/OD) [E];Seigfreid, Kim (NIH/OD) [E];Gallagher, Alissa (NIH/NINDS) [E];Warren, Margo (NIH/NINDS) [E];Wonders, Carl (NIH/NINDS) [E];Meltzer, Abbey (FNIH) [T];Canet-Aviles, Rosa (FNIH) [T]
Subject: RE: News Release for AMP PD is now live

Great news! Thanks, Renate!

From: Myles, Renate (NIH/OD) [E]
Sent: Tuesday, January 30, 2018 10:05 AM
To: Collins, Francis (NIH/OD) [E] (b) (6); Tabak, Lawrence (NIH/OD) [E] (b) (6) Wolinetz, Carrie (NIH/OD) [E] (b) (6) Koroshetz, Walter (NIH/NINDS) [E] (b) (6); Freire, Maria (FNIH) [T] <mfreire@fnih.org>; Wholley, David (FNIH) [T] <dwholley@fnih.org>; Hallett, Adrienne (NIH/OD) [E] (b) (6)
Cc: Burklow, John (NIH/OD) [E] (b) (6); Prince, Scott (NIH/OD) [E] (b) (6); Higgins, Lauren (NIH/OD) [E] (b) (6); Fine, Amanda (NIH/OD) [E] (b) (6)>; Wojtowicz, Emma (NIH/OD) [E] (b) (6); Seigfreid, Kim (NIH/OD) [E] (b) (6); Gallagher, Alissa (NIH/NINDS) [E] (b) (6); Warren, Margo (NIH/NINDS) [E] (b) (6); Wonders, Carl (NIH/NINDS) [E] (b) (6) Meltzer, Abbey (FNIH) [T] <ameltzer@fnih.org>; Canet-Aviles, Rosa (FNIH) [T] <rcanet-aviles@fnih.org>
Subject: News Release for AMP PD is now live

Good morning:

The news release on the Accelerating Medicines Partnership for Parkinson's Disease is now live and has been issued to the media: https://www.nih.gov/news-events/news-releases/nih-launches-partnership-improve-success-clinical-trials-patients-parkinsons-disease. We have also added an AMP PD page on the AMP website: https://www.nih.gov/research-training/accelerating-medicines-partnership-amp/parkinsons-disease and are featuring the announcement on the NIH.gov homepage: https://www.nih.gov/

Francis: Kim will send a proposed Tweet your way via separate email.

Best,
Renate

From: Wholley, David (FNIH) [T]
Sent: Sun, 28 Jan 2018 03:13:44 +0000
To: Baker, Rebecca (NIH/OD) [E]
Cc: Collins, Francis (NIH/OD) [E];Biarnes, Michael (FNIH) [T];Menetski, Joseph (FNIH) [T]
Subject: Re: Opioid White Paper First Draft Master Jan 27

You might want to tell them that just about the entire front end came from the PhRMA BMAC and F2F meeting notes documents they already have seen and edited.
So they concentrate their attention on the solutions sections.
Sent from my BlackBerry 10 smartphone.

From: Baker, Rebecca (NIH/OD) [E]
Sent: Saturday, January 27, 2018 9:15 PM
To: Wholley, David (FNIH) [T]
Cc: Collins, Francis (NIH/OD) [E]; Biarnes, Michael (FNIH) [T]; Menetski, Joseph (FNIH) [T]
Subject: RE: Opioid White Paper First Draft Master Jan 27

Thanks David and team,

I'll circulate this within our NIH team right away. I can't promise that we'll be able to get full review on all 60 pages from our leadership group within 2-3 business days, but will send major feedback your way in advance of the Feb 1 date for sharing with Rich.

Thanks again for all the hard work that went into this!

Rebecca

From: Wholley, David (FNIH) [T]
Sent: Saturday, January 27, 2018 7:51 PM
To: Baker, Rebecca (NIH/OD) [E] (b) (6)
Cc: Collins, Francis (NIH/OD) [E] (b) (6); Biarnes, Michael (FNIH) [T] <mbiarnes@fnih.org>; Menetski, Joseph (FNIH) [T] <jmenetski@fnih.org>
Subject: Opioid White Paper First Draft Master Jan 27
Importance: High

Rebecca, here is the first draft of the Opioids Partnership White Paper to take through NIH review. It contains everything except the Executive Summary, which we are working on in parallel (and essentially will just repeat what is in the document, compressed into two pages). We'll send that along separately when it is finished.

It's a big document, and final edits took us all day, so I apologize we were not able to get it out this morning.

Francis asked for an early look in our last NIH opioid team meeting, and given the lateness of the hour, I am copying him directly on this as well. Please send edits to me and Mike Biarnes and copy Joe Menetski at your earliest convenience. Rich M. has still asked for something on Feb. 1 so it can be sent

to the CEOs in time for the Feb. 7 meeting. FYI I am sending this now also to the co-chairs, to FDA, and to PhRMA as we agreed, for their initial edits.

Thanks for your patience

David

From: Wholley, David (FNIH) [T]
Sent: Mon, 29 Jan 2018 03:43:48 +0000
To: Collins, Francis (NIH/OD) [E]
Cc: Biarnes, Michael (FNIH) [T];Menetski, Joseph (FNIH) [T];Tabak, Lawrence (NIH/OD) [E];Baker, Rebecca (NIH/OD) [E];Wolinetz, Carrie (NIH/OD) [E]
Subject: RE: Opioid White Paper First Draft Master Jan 27

Francis,

I am glad you liked the white paper overall, and that our push to integrate the OUD and pain components appears to have been successful. I have looked through your comments, and can certainly incorporate the changes you suggest on in-kind contribution rules, frequency of meetings, etc. Yes, the pilot survey was successful at least judging by the reactions of Chris Flores and others—we'll send you a summary on that tomorrow. We can consider further whether it is worth mentioning the pilot as a detail—my instincts are not to include it given it is a temporal detail, but to move on and get the survey done as promised in the document.

As for your bigger questions on the budget: yes, these numbers are very much reflective of the "all hands on deck" approach we've been promoting, and all of the numbers you see were pressure tested with the entire Working Groups. The biomarkers numbers reflect the desire of the group to take what might be called a 'learn and confirm' approach to biomarker development given the current state of biomarker candidates in pain and the need to demonstrate an efficient approach—begin with literature searches, retrospective studies, then proceed to prospective studies based on earlier evidence. And yes, the group discussed several times the need to include realistic numbers for imaging, and had some pretty knowledgeable imaging people involved in coming up with these estimates. What you see is where they came out.

Similarly, we asked on the clinical trials network several times if the infrastructure costs were adequate:

(b) (4), (b) (5)

[redacted]

Given where we ended up on these costs, we went to the budget fallback we discussed in our call with you and the entire NIH group on the call we had before you left for Davos: make up the difference by adding more to the FMD category as a buy-up. The resulting total of $964M over five years was felt to be within acceptable striking distance of the $1B total number you have previously floated.

(b) (4), (b) (5)

[redacted]

(b) (4), (b) (5)

(b) (4), (b) (5) But it is what the groups came up with, and at this point unless someone can change industry's basic posture on what they are willing to contribute I do not think adding $X million to this or that category is going to make a material difference. If it is any consolation, Rich has said several times that he thinks that if we demonstrate progress and value on these proposals additional industry investments would indeed be possible.

I can discuss further by phone if you would like.

David

From: Collins, Francis (NIH/OD) [E]
Sent: Sunday, January 28, 2018 6:27 PM
To: Wholley, David (FNIH) [T] <dwholley@fnih.org>
Cc: Biarnes, Michael (FNIH) [T] <mbiarnes@fnih.org>; Menetski, Joseph (FNIH) [T] <jmenetski@fnih.org>; Tabak, Lawrence (NIH/OD) [E] (b) (6); Baker, Rebecca (NIH/OD) [E] (b) (6); Wolinetz, Carrie (NIH/OD) [E] (b) (6)
Subject: RE: Opioid White Paper First Draft Master Jan 27

Hi David et al.,

I had the chance to scan through the White Paper on the return trip from Davos. In general, this looks really well done – compelling presentation of scientific opportunities and how they can be tackled by the partnership. I really like how the OUD and pain components are melded together.

I made a few edits on the document, but didn't try to be very detailed. See attached.

(b) (5)

FC

From: Wholley, David (FNIH) [T]
Sent: Saturday, January 27, 2018 7:51 PM
To: Baker, Rebecca (NIH/OD) [E] (b) (6)
Cc: Collins, Francis (NIH/OD) [E] (b) (6)>; Biarnes, Michael (FNIH) [T] <mbiarnes@fnih.org>; Menetski, Joseph (FNIH) [T] <jmenetski@fnih.org>
Subject: Opioid White Paper First Draft Master Jan 27
Importance: High

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Thanks for your patience

David

From: Wholley, David (FNIH) [T]
Sent: Thu, 25 Jan 2018 02:28:43 +0000
To: Collins, Francis (NIH/OD) [E];Tabak, Lawrence (NIH/OD) [E];Koroshetz, Walter (NIH/NINDS) [E];Volkow, Nora (NIH/NIDA) [E];Wolinetz, Carrie (NIH/OD) [E];Porter, Linda (NIH/NINDS) [E];Stein, Jack (NIH/NIDA) [E];Baker, Rebecca (NIH/OD) [E]
Cc: Biarnes, Michael (FNIH) [T];Menetski, Joseph (FNIH) [T]
Subject: Update on Opioid and Pain white paper

Dear All:

As you will recall the white paper timeline spreadsheet that we provided ahead of last week's opioids partnership call said we'd try to have the white paper sent out to you and all working group members for review today (24th) or tomorrow (25th) so you can provide input prior to final review by Francis and PhRMA. As some of you know, on yesterday's Biomarkers & Endpoints working group call there were still some disagreements on a number of points that the group raised that we are working expeditiously to address with help from Jack's team and our co-chairs. Given the nature of some of the feedback, we felt it was necessary to schedule another short call with the Biomarkers & Endpoints working group for tomorrow morning to ensure that our revisions accurately captured the working group discussion. We are also working on refining final budget estimates and a few other issues, such as suitable language for a brief section on FDA's involvement. As such, while we will continue to push to get the white paper distributed tomorrow night, in all likelihood the white paper will be sent out late on Friday.

As you can imagine, we are very heads down on this. Thanks, David

From: Wholley, David (FNIH) [T]
Sent: Fri, 19 Jan 2018 19:35:58 +0000
To: Moscicki, Richard
Cc: Collins, Francis (NIH/OD) [E];Baker, Rebecca (NIH/OD) [E]
Subject: FDA involvement in the opioids partnership

Rich,
I had a chance to catch up with Francis and his team today and brought up the idea of a statement from FDA that could be incorporated into the white paper. It turns out that as part of Francis's conversation with Scott Gottlieb last week Scott promised to incorporate FDA's thoughts on supporting for new regulatory pathways for OUD and pain into an actual guidance that could then be referenced in the paper. He said this could be done relatively quickly, although not sure what that means in practice. Question for you is whether you think that will work to satisfy the interest you heard from the BMAC, or do we need to consider another course?

Thanks,
David

David Wholley
Director, Research Partnerships
Foundation for the National Institutes of Health
(301) 594-6343
fnih.org
11400 Rockville Pike Suite 600 North Bethesda, MD 20852

2017 Gold Stevie Award Winner for Organization of the Year

From: Wholley, David (FNIH) [T]
Sent: Fri, 19 Jan 2018 20:26:00 +0000
To: Collins, Francis (NIH/OD) [E];Baker, Rebecca (NIH/OD) [E]
Subject: Fw: FDA involvement in the opioids partnership

Please see below. How do we convey this specifically to Scott?
Sent from my BlackBerry 10 smartphone.

From: Moscicki, Richard <rmoscicki@phrma.org>
Sent: Friday, January 19, 2018 3:02 PM
To: Wholley, David (FNIH) [T]
Subject: RE: FDA involvement in the opioids partnership

David, that is great news. If we can work out how to get that into the white paper it would go a long way. (b) (4)

(b) (4)

(b) (4) I think I could then very comfortably make the case to BMAC that they have been heard and this is going in the right direction. I think we can get by then without seeking legislative approaches, which I worry might be counterproductive.
While I have you, I am setting things up for the board meeting and our subcommittee that will review and endorse the partnership for a subsequent board vote. The key component I have to frame is the proposed cost for industry, ie the budget. Could I communicate with the chairs of the working groups to discuss the budgets? Rich.

From: Wholley, David (FNIH) [T] [mailto:dwholley@fnih.org]
Sent: Friday, January 19, 2018 2:36 PM
To: Moscicki, Richard <rmoscicki@phrma.org>
Cc: Collins, Francis (NIH/OD) [E] (b) (6); Baker, Rebecca (NIH/OD) [E]
(b) (6)
Subject: FDA involvement in the opioids partnership

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David

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Director, Research Partnerships
Foundation for the National Institutes of Health
(301) 594-6343
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11400 Rockville Pike Suite 600 North Bethesda, MD 20852

2017 Gold Stevie Award Winner for Organization of the Year

From: Wholley, David (FNIH) [T]
Sent: Fri, 19 Jan 2018 21:29:46 +0000
To: Collins, Francis (NIH/OD) [E];Baker, Rebecca (NIH/OD) [E]
Subject: Fw: FDA involvement in the opioids partnership

Just in case you were wondering here is my reply to the second half of his note.
Sent from my BlackBerry 10 smartphone.

From: Moscicki, Richard <rmoscicki@phrma.org>
Sent: Friday, January 19, 2018 3:28 PM
To: Wholley, David (FNIH) [T]
Subject: RE: FDA involvement in the opioids partnership

Sure!

From: Wholley, David (FNIH) [T] [mailto:dwholley@fnih.org]
Sent: Friday, January 19, 2018 3:24 PM
To: Moscicki, Richard <rmoscicki@phrma.org>
Subject: Re: FDA involvement in the opioids partnership

I think it is just a little early for that as we have not heard any real numbers from biomarkers group and are still refining the others. I think we'd be in good shape for you to do that (or just look at what we've come up with from the Working Group discussions) by Wed or so. Will that work for you?

Sent from my BlackBerry 10 smartphone.

From: Moscicki, Richard
Sent: Friday, January 19, 2018 3:02 PM
To: Wholley, David (FNIH) [T]
Subject: RE: FDA involvement in the opioids partnership

David, that is great news. If we can work out how to get that into the white paper it would go a long way. (b) (4)

(b) (4)

(b) (4) I think I could then very comfortably make the case to BMAC that they have been heard and this is going in the right direction. I think we can get by then without seeking legislative approaches, which I worry might be counterproductive.
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From: Wholley, David (FNIH) [T] [mailto:dwholley@fnih.org]
Sent: Friday, January 19, 2018 2:36 PM
To: Moscicki, Richard <rmoscicki@phrma.org>
Cc: Collins, Francis (NIH/OD) [E] (b) (6); Baker, Rebecca (NIH/OD) [E] (b) (6)
Subject: FDA involvement in the opioids partnership

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Thanks,
David

David Wholley
Director, Research Partnerships
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11400 Rockville Pike Suite 600 North Bethesda, MD 20852

2017 Gold Stevie Award Winner for Organization of the Year

From: Wholley, David (FNIH) [T]
Sent: Fri, 19 Jan 2018 20:27:31 +0000
To: Collins, Francis (NIH/OD) [E]
Cc: Baker, Rebecca (NIH/OD) [E]
Subject: Fw: Governance for opioids

FYI on the other issue I mentioned today.
Sent from my BlackBerry 10 smartphone.

From: Moscicki, Richard <rmoscicki@phrma.org>
Sent: Friday, January 19, 2018 3:25 PM
To: Wholley, David (FNIH) [T]
Subject: RE: Governance for opioids

This is admittedly new territory for me David. I hope not, or perhaps provisionally fund but ask for a change. I still think its ok to put it in. Rich.

From: Wholley, David (FNIH) [T] [mailto:dwholley@fnih.org]
Sent: Friday, January 19, 2018 3:20 PM
To: Moscicki, Richard <rmoscicki@phrma.org>
Subject: Re: Governance for opioids

(b) (4)

Sent from my BlackBerry 10 smartphone.

From: Moscicki, Richard
Sent: Friday, January 19, 2018 3:06 PM
To: Wholley, David (FNIH) [T]
Subject: RE: Governance for opioids

I understand the issue, personally I am comfortable, I am not fully able to say whether all the companies will feel the same way. Having said that, I think we should write it that way with the caveat "in order to avoid possible conflict of interest or perceived conflict of interest..." Then lets see how it flies when the CEOs see it, I will explain of course. Similarly, I may have to come back on budget when they see that. Rich.

From: Wholley, David (FNIH) [T] [mailto:dwholley@fnih.org]
Sent: Friday, January 19, 2018 2:54 PM
To: Moscicki, Richard <rmoscicki@phrma.org>
Subject: Governance for opioids

Rich, as you no doubt know by now we are proposing to govern the execution of the opioids partnership much the way we have AMP and PACT: with one or more operationally focused Steering Committees (with NIH scientists and at least one scientific lead from each company) reporting into an Executive Committee (likely with Francis, Nora Volkow, Walter Koroshetz, three industry execs, and a patient representative at minimum). For the SCs we usually provide a voting mechanism where each company gets one vote on the private sector side and where NIH (plus non-profits if any) can divvy up votes as

they wish, but where the weight of votes is distributed equally (50% NIH, 50% industry) regardless of the number of representatives on each side. Ties at the SC level go to the EC (and we have usually not had to specify what happens if there is a tie there, as the assumption is that the EC will work things out; in AMP anyway the EC has slightly more NIH reps). I have been thinking about all the controversy about opioids and the resulting need to be especially careful with optics, and would like to propose that for this partnership alone we change the language to state that votes will still take place, but that NIH has the ultimate deciding vote in the event of a split, so that if there are any concerns about conflicts of interest or the integrity of the science NIH in fact can veto a decision regarding a particular project or use of funds. I doubt we'd ever use it, but it would be useful to be able to point to it if (or maybe it is when) the inevitable question arises about such a thing from the media. I thought this might be something in fact that industry might not only acquiesce in, but prefer under the circumstances. What do you think?

David

David Wholley
Director, Research Partnerships
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(301) 594-6343
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2017 Gold Stevie Award Winner for Organization of the Year

From: Wholley, David (FNIH) [T]
Sent: Mon, 29 Jan 2018 15:01:49 +0000
To: Collins, Francis (NIH/OD) [E];Tabak, Lawrence (NIH/OD) [E];Baker, Rebecca (NIH/OD) [E];Wolinetz, Carrie (NIH/OD) [E]
Cc: Menetski, Joseph (FNIH) [T];Biarnes, Michael (FNIH) [T]
Subject: FW: Opioids White Paper draft

FYI, see below.

From: Moscicki, Richard [mailto:rmoscicki@phrma.org]
Sent: Monday, January 29, 2018 8:34 AM
To: Wholley, David (FNIH) [T] <dwholley@fnih.org>
Subject: RE: Opioids White Paper draft

Thanks David, we will still need to discuss the budget piece. Our Finance committee will review the $50 million per year figure today. We discussed finding a way to move some of the high costs of the first project into "optimal". Rich.

From: Wholley, David (FNIH) [T]
Sent: Wed, 14 Feb 2018 14:02:11 +0000
To: Collins, Francis (NIH/OD) [E];Baker, Rebecca (NIH/OD) [E];Tabak, Lawrence (NIH/OD) [E];Porter, Linda (NIH/NINDS) [E];Stein, Jack (NIH/NIDA) [E];Wolinetz, Carrie (NIH/OD) [E]
Cc: Koroshetz, Walter (NIH/NINDS) [E];Volkow, Nora (NIH/NIDA) [E];Biarnes, Michael (FNIH) [T];Menetski, Joseph (FNIH) [T]
Subject: Fw: communication plan for NIH/PhRMA PPP on Opioid Crisis and potential contribution by JPET

See below. Ken represented Astellas in working group discussions. Copying the rest of the NIH group. David
Sent from my BlackBerry 10 smartphone.

From: Melencio, Cheryl (FNIH) [T] <cmelencio@fnih.org>
Sent: Wednesday, February 14, 2018 8:42 AM
To: Wholley, David (FNIH) [T]; Menetski, Joseph (FNIH) [T]; Biarnes, Michael (FNIH) [T]
Subject: FW: communication plan for NIH/PhRMA PPP on Opioid Crisis and potential contribution by JPET

fyi

Cheryl Melencio
Executive Assistant, Research Partnerships
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2017 Gold Stevie Award Winner for Organization of the Year

From: Marek, Gerard [mailto:gerard.marek@astellas.com]
Sent: Wednesday, February 14, 2018 12:05 AM
To: Melencio, Cheryl (FNIH) [T] <cmelencio@fnih.org>; Koroshetz, Walter (NIH/NINDS) [E] (b) (6); Chin@phrma.org; (b) (6); Volkow, Nora (NIH/NIDA) [E] (b) (6)
Cc: Tew, Kenneth D. <tewk@musc.edu>; Blumer, Joe B (blumerjb@musc.edu) <blumerjb@musc.edu>
Subject: communication plan for NIH/PhRMA PPP on Opioid Crisis and potential contribution by JPET

On behalf of The Journal of Pharmacology and Experimental Therapeutics editor Kenneth Tew, I wanted to extend an offer for JPET to play a role in the dissemination of the goals and plans for the NIH/PhRMA PPP on Opioid Crisis. Specifically, the manner in which JPET believes it could provide a contribution would be to dedicate an issue this year to the opioid crisis and the two-pronged need to develop treatments for opioid use/overdoses as well as novel non-opioid analgesics. At a minimum, I would envision an article contributed by NIDA dealing with the range of issues addressing developing treatments for opioid use/overdoses. Similarly, I would imagine a contribution from NINDS laying out issues related to developing novel non-opioid

analgesics. Then we would want to round out the issue with research articles and other additional focused review articles geared toward these issues.

We would be most interested in hearing from you if this might fit in as part of your general communication plan and if there are other issues that should be highlighted.

Best wishes
Gerard

Gerard J Marek, MD, PhD

Associate Editor, JPET

Executive Medical Director
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From: Wholley, David (FNIH) [T]
Sent: Thu, 15 Feb 2018 20:36:10 +0000
To: Collins, Francis (NIH/OD) [E];Tabak, Lawrence (NIH/OD) [E];Koroshetz, Walter (NIH/NINDS) [E];Volkow, Nora (NIH/NIDA) [E];Wolinetz, Carrie (NIH/OD) [E];Porter, Linda (NIH/NINDS) [E];Stein, Jack (NIH/NIDA) [E];Baker, Rebecca (NIH/OD) [E]
Cc: Menetski, Joseph (FNIH) [T];Canet-Aviles, Rosa (FNIH) [T]
Subject: Fw: Opioid PPP

Sent from my BlackBerry 10 smartphone.

From: Moscicki, Richard <rmoscicki@phrma.org>
Sent: Thursday, February 15, 2018 3:16 PM
To: Collins, Francis (NIH/OD) [E]; Wholley, David (FNIH) [T]; Baker, Rebecca (NIH/OD) [E]
Subject: Opioid PPP

I wanted to let you know that the FDABRC committee of the PhRMA board has endorsed the PPP and recommended that it be presented to the board after satisfactory resolution of the governance and the valuation of in kind contributions (nature, amount, and assigned value). Additional requirements are an agreement that government shall contribute at least 50% of the cost and assigned resources and that there be a review at the end of three years as to the progress and direction of the partnership. The committee also asked for a communication plan to be developed as part of the partnership. Rich.

From: Wholley, David (FNIH) [T]
Sent: Tue, 20 Feb 2018 14:54:19 +0000
To: Collins, Francis (NIH/OD) [E];Tabak, Lawrence (NIH/OD) [E];Stein, Jack (NIH/NIDA) [E];Koroshetz, Walter (NIH/NINDS) [E];Porter, Linda (NIH/NINDS) [E];Volkow, Nora (NIH/NIDA) [E];Wolinetz, Carrie (NIH/OD) [E];Baker, Rebecca (NIH/OD) [E]
Cc: Menetski, Joseph (FNIH) [T];Biarnes, Michael (FNIH) [T]
Subject: FW: Partnership to Address The Opioids Crisis - White Paper Final Draft
Attachments: BIO_HPCP_Series-Pain_Addiction_2018-02-08.pdf

FYI, in case you'd not seen this.

From: Dworkin, Robert [mailto:Robert_Dworkin@URMC.Rochester.edu]
Sent: Saturday, February 17, 2018 11:46 AM
To: Biarnes, Michael (FNIH) [T] <mbiarnes@fnih.org>
Cc: Wholley, David (FNIH) [T] <dwholley@fnih.org>; Menetski, Joseph (FNIH) [T] <jmenetski@fnih.org>
Subject: RE: Partnership to Address The Opioids Crisis - White Paper Final Draft

in case you don't have it, was just sent a copy of the attached, which has a lot of very relevant information….

^^
Robert H. Dworkin, PhD
Professor of Anesthesiology and Perioperative Medicine, Neurology, and Psychiatry
Director, Anesthesiology Clinical Research Center
Director, Analgesic, Anesthetic, and Addiction Clinical Trial Translations, Innovations, Opportunities, and Networks (ACTTION), a public-private partnership with the FDA
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From: Biarnes, Michael (FNIH) [T] [mailto:mbiarnes@fnih.org]
Sent: Monday, February 12, 2018 10:30 AM
Cc: Wholley, David (FNIH) [T] <dwholley@fnih.org>; Menetski, Joseph (FNIH) [T] <jmenetski@fnih.org>
Subject: Partnership to Address The Opioids Crisis - White Paper Final Draft

Dear Opioids Partnership Working Group Members,

Thank you all again for your extraordinary contributions over the past few months to the white paper for the opioids partnership. We are pleased to send you the final draft of the White Paper. Since our last Working Group teleconferences two weeks ago, we have benefited from extensive additional review, edits, and comments from your working group Co-Chairs as well as leadership of and participants from NIH, FDA, and PhRMA. Given all this, we would ask that you limit any additional feedback to any truly major comments or concerns you need to bring to our attention, rather than focusing on specific stylistic or language suggestions. (Of course, please do let us know if you see typos or anything that is factually incorrect.)

You will no doubt notice that a fair amount of proposed draft language in the governance sections that was included in some of our earlier discussions has been removed from the text for the time being. It has been determined that these sections must undergo further legal review and policy review by NIH before they can be appropriately shared in print, and some details could possibly change. However rest assured that all of the valuable inputs we had in our working group discussions about governance are still very much part of the conversation, and you will be able to see the final language once it has been reviewed and approved.

Please provide any feedback you might have to Michael Biarnes and cc: David Wholley by COB this Thursday February 15. This remains a confidential draft document until finalized: we ask that you please not copy or distribute it further until a final version has been provided. Thanks again for all of your help.

Best,

Mike

Michael Biarnes
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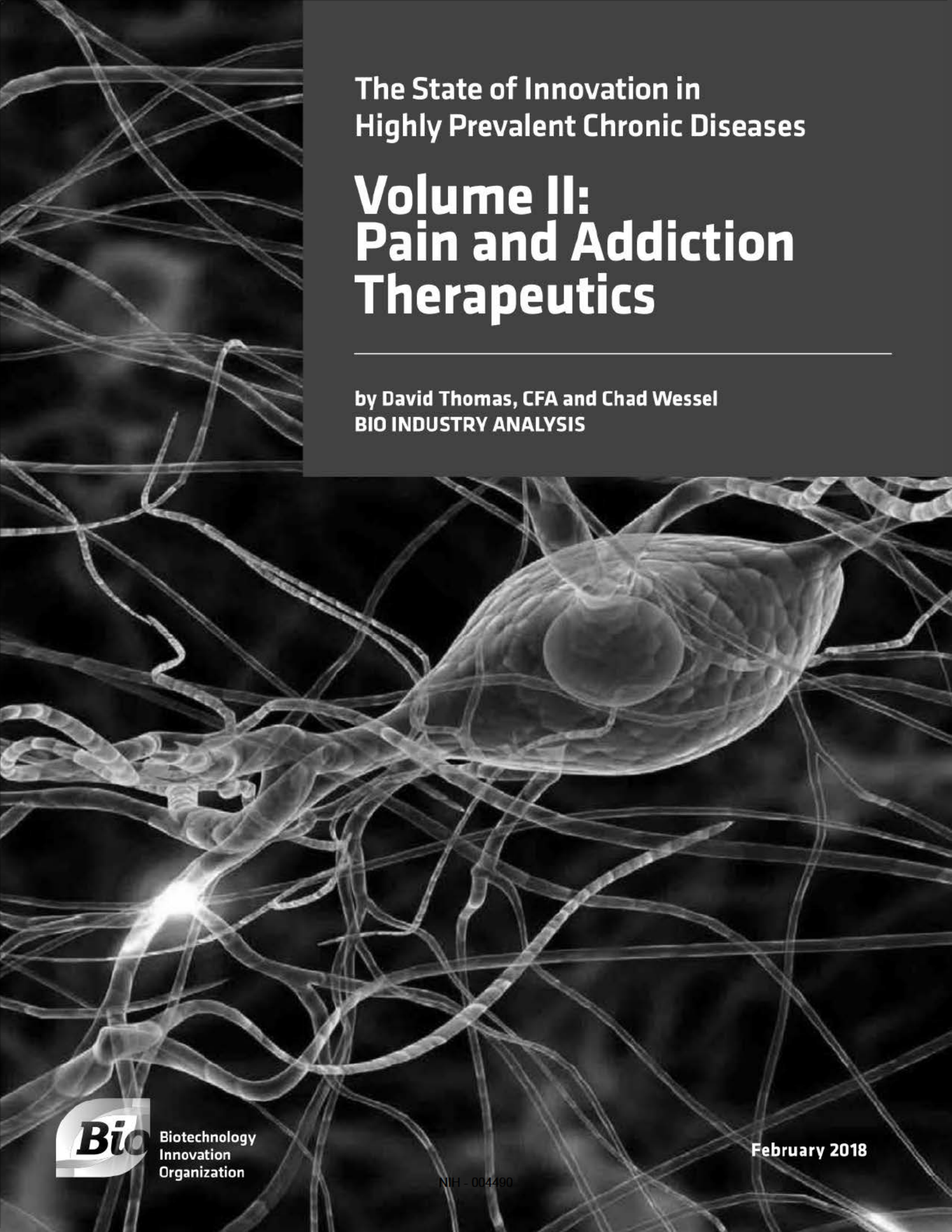

The State of Innovation in Highly Prevalent Chronic Diseases

Volume II: Pain and Addiction Therapeutics

by David Thomas, CFA and Chad Wessel
BIO INDUSTRY ANALYSIS

Biotechnology Innovation Organization

February 2018

NIH - 004490

Introduction

The following report is the second in a series on the current funding and R&D landscape of highly prevalent, chronic diseases. In our previously published research, emerging company investment for drug development in many of these common diseases was shown to be declining over the last decade and low relative to the prevalence and cost of these diseases (**Figure 1**).[1] The persistence of this trend could have implications for the future output of innovative medicines in these disease areas. The cause for concern is magnified by the impact these chronic disease areas are having on the overall healthcare system in the US. Thus, it is important that barriers to therapeutic innovation are identified and removed.

This volume takes an in depth look at the state of innovation in pain as well as addiction therapeutics. Chronic pain affects as many as 100 million people in the US alone.[2] Total economic and direct healthcare costs for treating pain in the US have been estimated to be as high as $635 billion annually, higher than the costs for cancer, Alzheimer's, or cardiovascular disease.[3] Addiction to drugs and alcohol affects more than 23 million Americans and continues to rise, in part due to abuses of pain medications.[4] Total economic and direct healthcare costs for substance abuse is an alarming $700 billion per year.[5]

Herein, we analyze all drugs marketed in the US for pain and addiction, as well as potential future drugs that are progressing through the clinical pipeline to meet the urgent needs of patients. The pipeline analysis aims to assess the depth and breadth of innovation given the large unmet need in pain management and addiction treatment. Historical clinical success rates and failed mechanistic strategies are also identified, as well as trends in venture financing and investment into new clinical trials.

Key Takeaways

- There have been only two novel chemical entities FDA approved to treat pain over the past decade.[6]
- The industry-wide pain pipeline consists of 220 clinical-stage drug programs, with 125 of these testing novel chemical entities in the clinic, 87% of which are for non-opioid receptors. These are relatively low numbers when compared to the current pipeline for oncology (2,617 total programs and 1,700 novel drug clinical-stage programs).
- Over the past decade, the biopharmaceutical industry has been working to develop abuse deterrent formulations, with 142 clinical trials initiated and 12 FDA approvals for abuse deterrent pain products.
- Clinical success in pain drug development has been extremely difficult for novel drugs, with only a 2% probability of FDA approval from phase I, compared to an overall 10% success rate across all diseases.
- Private company investment, as measured by venture capital into US companies with lead stage programs in pain, is 3.6% of total drug development venture funding. For venture funding of novel R&D, pain has received 17 times less venture capital than oncology over the last decade.
- There are only 15 active clinical-stage programs with novel compounds intended for addiction treatment: 10 for substance abuse, two for alcohol, and three for smoking cessation.
- Venture investment for addiction drug R&D is nearly non-existent.

1 Thomas, D., Wessel, C. (2008) Emerging Company Trend Report, BIO Industry Analysis. (2017) (www.bio.org/iareports)
2 Medical Expenditure Panel Survey (MEPS), (2008). Definition of chronic includes joint pain or arthritic pain.
3 Gaskin, D, Richard, P. Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education, and Research. The Economic Costs of Pain in the United States. Institute of Medicine (US) Committee on Advancing Pain Research, Care, and Education. Washington (DC): National Academies Press (US); (2011).
4 Defining The Addiction Treatment Gap. Open Society Foundations (2010).
5 https://www.drugabuse.gov/related-topics/trends-statistics
6 Since 2007, novel chemical entities approved in pain, with no prior approval history, are: 1) milnacipran, an SNRI drug approved for depression ex-US since the 1990s, received its first FDA approval for fibromyalgia in 2009 and 2) tapentadol, a novel opioid drug FDA approved in 2010. The majority of chemical entities approved in pain since 2007 have been reformulations or have pre-2007 US market history.

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DISEASE PREVALENCE AND HEALTHCARE COST VS. VENTURE CAPITAL FUNDING FOR HIGHLY PREVALENT CHRONIC DISEASES

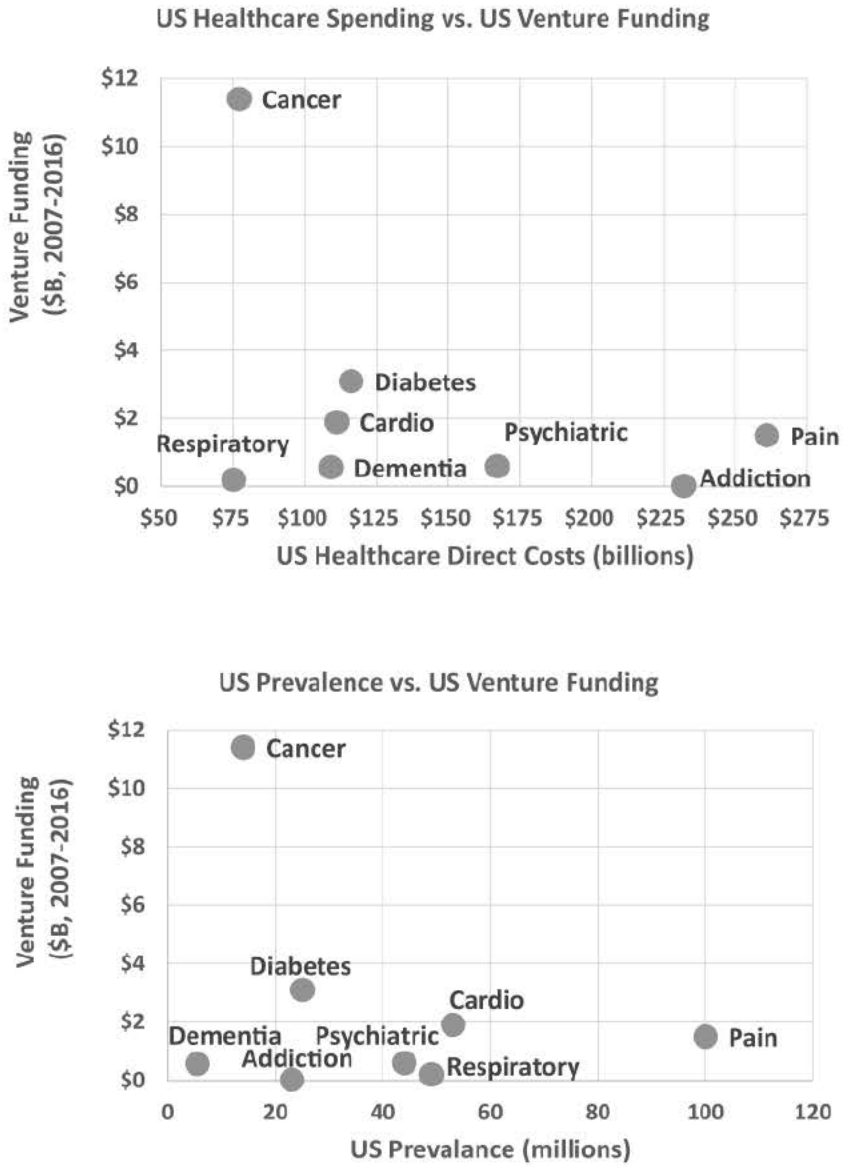

Figure 1. Prevalence and Cost vs. Venture Capital Funding 2007-2016 for Oncology, Psychiatry and other highly prevalent, chronic diseases. [Source for prevalence: Cardiovascular: 2015 data from Circulation, Heart Disease and Stroke Statistics – 2016 update; Psychiatric Disorders: 2010 data from NAMI for "Mental Illness"; Endocrine: 2007 data compiled by CDC; Cancer: 2014 data from SEER, Pain: MEPS, 2008. Source for healthcare cost: Health Affairs, 35, No. 6 (2016), Pain: The Journal of Pain, 2012. Source of venture data: BIO Industry Analysis, Emerging Company Trend Report, 2017.]

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Overview of FDA Approved Pain Therapeutics

Pain can be classified into either **nociceptic** pain (the more common pain associated with injury, heat, and other external factors), and **neuropathic** pain, which arises internally from damaged nerves or other diseases affecting the somatosensory system. Migraine headaches tend to be classified as either a complex mix of both of these types, or a complex neuropathic pain.[7] Nociceptic, neuropathic, and migraine pain can each be chronic in nature and each type affects millions of people globally. In this report, we consider treatments for all indications for pain under development: chronic, moderate to severe, postsurgical, and acute pain, as well as cancer pain, inflammatory pain, arthritic pain, fibromyalgia, neuropathy, sciatica, and migraine. We excluded drugs used for general anesthesia in the surgical setting but include local anesthetic agents, as some of these reformulated products have applications in the chronic setting.

FDA Approved Medicines for Pain

Analyzing the EvaluatePharma and Biomedtracker databases for FDA approved drugs indicated for treating pain, we found 77 novel chemical entities that treat pain based on 12 mechanistic strategies (see **Figure 2)**.[8] The majority of these drugs are now available as generic medicines, either in their original formulation or as new formulations (*e.g.,* different salt forms, extended release capsules, or as combination products). Roughly a third of these were first marketed prior to 1950, and two thirds prior to the year 2000. In the last decade, only two novel chemical entities, with no prior approval history, have been approved for pain treatment: 1) milnacipran, an SNRI drug approved for depression ex-US since the 1990s, received its first FDA approval for fibromyalgia in 2009 and 2) tapentadol, a novel opioid drug FDA approved in 2010. The majority of chemical entities approved in pain since 2007 have been reformulations or have pre-2007 US market history.[9]

When examining the 12 mechanistic strategies, the most prescribed pain drugs in the United States fall into the following three categories: 1) cyclooxygenase inhibitors (NSAIDs and other prostaglandin modulators), 2) opioid receptor modulators ("opioids"), and 3) direct sodium channel blockers (the "caines," such as lidocaine and benzocaine). Beyond these three mechanistic strategies, each of which has a long market history, the nine other categories tend to be more specialized in the type of pain being treated, with five strategies only having one drug representative (listed in **Figure 2**).

Aspirin is an example of a drug in the category of cyclooxygenase inhibitors, generally used to treat mild to moderate pain; aspirin has been on the market since the early 1900s.[10] Since the turn of the 20th century, this category of drugs has gone through three development periods. First was the approval of acetaminophen (Tylenol) in 1955 (its precursor phenacetin was introduced in the early 1900s but withdrawn in 1983 for its "high potential for misuse and its unfavorable benefit-to-risk ratio"[11]). The second development was a new class of NSAIDs in the 1970s and 1980s, which included ibuprofen (Advil, Motrin) and naproxen (Aleve). In the late 1990s, a third class was introduced as industry researchers created more selective inhibitors for a specific cyclooxygenase enzyme (COX-2) known to be involved in peripheral inflammation. However, while innovative at the biochemical level, drugs in this class were withdrawn from the market due to cardiovascular toxicity issues that occurred with certain patients (*e.g.,* celecoxib (Celebrex), rofecoxib (Vioxx), and valdecoxib (Bextra)).

The second category, opioid receptor modulators, includes medicines to treat more severe pain. These have a long history dating back thousands of years, beginning with use of poppy resin extract. In the 1800s, the active compounds in poppy seed resin (morphine and codeine) were isolated and, by the turn of the century, sold in purified form. By the early 1900s, not only were purified morphine and codeine sold, but so were related semi-synthetic compounds heroin, oxycodone (the active ingredient of today's Oxycontin), oxymorphone, and several other opioids. In the 1940s and 1950s, new fully synthetic opioids prodine and meperidine (Demerol) were introduced, having little structural similarity to the semi-synthetic opioids but maintaining similar potency. From 1960 to the 1980s, more potent synthetic opioid receptor modulators were brought the market including fentanyl and carfentanyl (respectively 100 and 10,000 times more potent than morphine). By 1990, 18 active opioid substances were introduced to the U.S. market, many of which are still widely used today, albeit in reformulated composition.

7 Chakravarty, A., et. al. Migraine, neuropathic pain and nociceptive pain: towards a unifying concept. Med Hypotheses. 74(2):225-31 (2010)

8 EvaluatePharma database (www.evaluategroup.com) accessed December 2017, Bomedtracker (biomedtracker.com) accessed December 2017. Other eferences include Advokat, C., et al. Julien's Primer of Drug Action, 13th edition (2014) and Waller, D., et al. Medical Pharmacology & Therapeutics, 4th edition (2014)

9 Reformulations and repurposed drugs are categorized as "non-NME" in the Biomedtracker database. Examples of FDA approved chemical entities with prior approval history include pregabalin (Lyrica) and duloxetine (Cymbalta), originally approved in depression, approved for Fibromyalgia in 2007 and 2009; Botox, approved for wrinkles in 2002, received an sBLA approval in 2010; Capsaicin was sold OTC prior to the 2009 FDA approval of Qutenza in postherpetic neuralgia (PHN).

10 Acetylsalicylic acid (Aspirin) is a derivative of salicylic acid, a cyclooxygenase inhibitor also marketed in late 1800s. Salicylic acid is the key ingredient in willow tree extract and has been used for thousands of years to treat pain.

11 Federal Register of October 5, 1983 (48 FR 45466). https://www.fda.gov/ohrms/dockets/ac/98/briefingbook/1998-3454B1_03_WL37.pdf

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The third category includes medicines that target voltage-gated sodium channel modulation (*e.g.*, inhibition of sodium release and electrical signaling), which have been primarily used in acute setting as local analgesics. The currently marketed chemical entities were introduced a century ago as chemists designed non-addictive substitutes for cocaine. For example, benzocaine, first synthesized in 1890, is still available over the counter (OTC) to treat skin and dental pain. Some of these chemical entities have been formulated for more chronic use. An example is bupivacaine in a liposome formulation that can be used for postsurgical analgesia, reducing the need for opioid use.

UNIQUE CHEMICAL ENTITIES MARKETED IN THE US FOR PAIN

	Mechanistic Strategy	Physiological Outcome	API Count	Unique Chemical Entities on Market
1	cyclooxygenase inhibition	inhibition of prostaglandin synthesis, leading to vasoconstriction and anti-inflammation	24	salicylate, aspirin, methyl salicylate, acetaminophen, ibuprofen, naproxen, fenoprofen, ketoprofen, flurbiprofen, nabumetone, indomethacin, nepafenac, etodolac, bromfenac, ketorolac, sulindac, diclofenac, meloxicam, piroxicam, oxaprozin, mefenamic acid, meclofenamate, tolmetin, diflunisal
2	opioid receptor modulation	inhibition of neurotransmitter and neuropeptide release	19	morphine, hydromorphone, oxymorphone, oxycodone, buprenorphine, codeine, hydrocodone, prodine, meperidine, fentanyl, sufentanil, levorphanol, pentazocine, butorphanol, nalbuphine, dezocine, tramadol, tapentadol
3	voltage-gated sodium channel modulation	inhibition of sodium release and electrical signalling	10	benzocaine, tetracaine, lidocaine, bupivacaine, ropivacaine, articaine, chloroprocaine, dibucaine, pramoxine, butamben
4	serotonin receptor agonists	indirect inhibition of CRGP, leading to vasoconstriction	9	ergotamine, dihydroergotamine, sumatriptan, almotriptan, eletriptan, frovatriptan, naratriptan, rizatriptan, zolmitriptan
5	monoamine modulation	sedative effect via multiple receptors/ transporters	4	droperidol, levomepromazine, duloxetine, milnacipran
6	voltage-gated calcium channel inhibition	inhibition of neurotransmitter and neuropeptide release	3	gabapentin, pregabalin, ziconotide
7	GABA modulation	increase in GABA or GABA-like CNS inhibition directly (GABA receptor) or indirectly (Glu receptors, etc.)	3	topiramate, valproic acid (divalproex), butalbital
8	adrenergic receptor antagonism	beta blocking mediated vasoconstriction	1	propranolol
9	phosphodiesterase inhibition	cAMP-inducing smooth muscle vasoconstriction	1	cilostazol
10	SNARE inhibition	blocks acetylchloline release and neurotransmission	1	onabotulinumtoxinA
11	vanilloid receptor modulation	inhibition of neurotransmitter and neuropeptide release	1	capsaicin
12	sodium channel inhibition with monamine modulation	sedative effect via multiple receptors/ transporters	1	carbamazepine

Figure 2. Unique FDA approved Active Pharmaceutical Ingredients (APIs) for pain still active as of January 2018 (prescription, generic, or OTC) categorized by primary mechanistic target strategy and physiological strategy. The list does not include herbal extracts and adjuvant medicines that assist the anti-pain compounds, drugs for general anesthesia for the surgical setting, and excludes enantiomer isolations, herbal extracts and supplements. Source: EvaluatePharma, Biomedtracker, fda.gov, company websites. (Drugs that were once sold in the US but are now discontinued (withdrawn due to side effects or deemed illegal by law) are not shown in this list. For example: the opioids heroin, anileridine, propoxyphene; cocaine for local anesthesia; three COX-2 inhibitors (celecoxib (Celebrex), rofecoxib (Vioxx), and valdecoxib (Bextra); the anti-pyretic propoxyphene, phenylbutazone, phenacetin (the precursor to Tylenol), NSAIDs benoxaprofen and phenylbutazone.)

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The fourth category, serotonin receptor agonists, is relatively new compared to the previously discussed mechanistic strategies. The first FDA approved drug in this class, sumatriptan, was approved in 1998 for migraine headaches. Eight more have been approved since then. These drugs work by activating specific serotonin receptors known as 5HT1B and 5HT1D and are indicated for migraine headaches. Activation of these receptors eventually leads to a dampening of neural calcitonin gene-related peptide (CRGP) production, and ultimately an attenuation of the vasodilation that accompanies headaches.[12] As will be described later, this CRGP pathway is a promising target for numerous Phase III product candidates in the pipeline today.

Category five, monoamine neurotransmitter modulators, include drugs that have psychiatric indications (*e.g.*, anti-psychotic, anti-depressant) that have also been utilized to treat pain. This is likely due to the breadth of targets these drugs impact. For example, some of these drugs have both transporter and receptor activity, as well as anti-histamine activity. One example is duloxetine (Cymbalta), a serotonin, norepinephrine reuptake inhibitor (SNRI) antidepressant, was approved by the FDA for peripheral diabetic neuropathic pain in 2005.

The direct voltage-gated calcium channel modulators (category 6) have been approved for use in neuropathic pain indications. Examples include conotoxin ziconotide, a small peptide derived from snail toxins prescribed since 2004 as a long-acting medicine for chronic pain, as well as gabapentin (Neurontin) and pregabalin (Lyrica) which have been used to treat chronic neuropathic pain since 2002 and 2004, respectively.[13]

The direct or indirect gamma-aminobutyric acid (GABA) stimulators make up category 7. GABA, a key inhibitory neurotransmitter in the brain that dampens nerve excitation, has also been the target of pain drugs. For example, butalbital, a direct GABA receptor agonist, mimics some of the effects that GABA has on the nervous system. The other drugs in this group are difficult to categorize as some of the drugs have ambiguous mechanisms in their GABA modulating activity. For example, topiramate has been proposed to antagonize glutamate receptors (ionotropic kainate type) as well as other pathways that lead to increased GABA. Topiramate was approved in 2004 for migraine prophylaxis. The GABA analog, valproic acid (divalproex), available since the 1970s, is also believed to increase GABA levels but the mechanism is not yet known.

Categories 8-12 each contain a single drug and each work in unique ways. Propanolol (8), on the market since the 1960s, works as a beta blocker (beta adrenergic receptor), leading to vasoconstriction and migraine prophylaxis. Phosphodiesterase inhibitor cilostazol (9) works through an indirect signaling pathway that leads to vasoconstriction. Botulinum toxin (10), marketed as Botox for headache pain in 2010, blocks the neurotransmission (synaptic vesicle release) of acetylcholine. Capsaicin (11) is the same active component of hot chili peppers and is the only compound approved that directly binds to the ionotropic vanilloid receptor. Its activity for pain derives from long exposure and desensitization of the nerve signaling. The last drug on the list, the anti-psychotic drug carbamazepine (12), works as a direct binder of sodium channels and, not surprising based on its structure, is a likely serotine reuptake inhibitor.

Current Clinical Pipeline in Pain

There has been progress over the last few decades in advancing our understanding of the biologic mechanisms underlying pain. As mentioned above, the serotonin receptor subtype 1B/1D inhibitors were a turn of the century example of newly defined targets spawned out of basic biological research followed by industrial breakthroughs in biochemical specificity. Since the last of these migraine-indicated triptans were approved, however, there has been relatively few new targets that have an FDA approved drug associated with them. The selective cyclooxygenase-2 (COX-2) inhibitors were another example of industry's progress in drug target selectivity. Unfortunately, the complexity of COX-2 tissue expression in non-targeted organs led this group to be withdrawn. After this period in the early 2000s there have been only a few examples of new drug class approvals in pain.

The current clinical pipeline includes 220 ongoing clinical programs for pain indications. Of these 220 programs, 125 have completely novel drugs indicated for pain. Furthermore, 87% of these novel programs are pursuing non-opioid receptor targets (See **Figure 3**).

[12] Durham, P. Calcitonin Gene-Related Peptide (CGRP) and Migraine, Headache; 46, S1 (2006) and Ahn, A. et.al. Where do triptans act in the treatment of migraine? Pain. 115(1-2): 1–4 (2005).

[13] Patel, R., et.al. Mechanisms of the gabapentinoids and α2 δ-1 calcium channel subunit in neuropathic pain. Pharmacol Res Perspect. Apr; 4(2) (2016)

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2017 DRUG PIPELINE FOR PAIN
125 NOVEL DRUG (NME/BIOLOGIC), 95 REFORMULATION (NON-NME) PROGRAMS

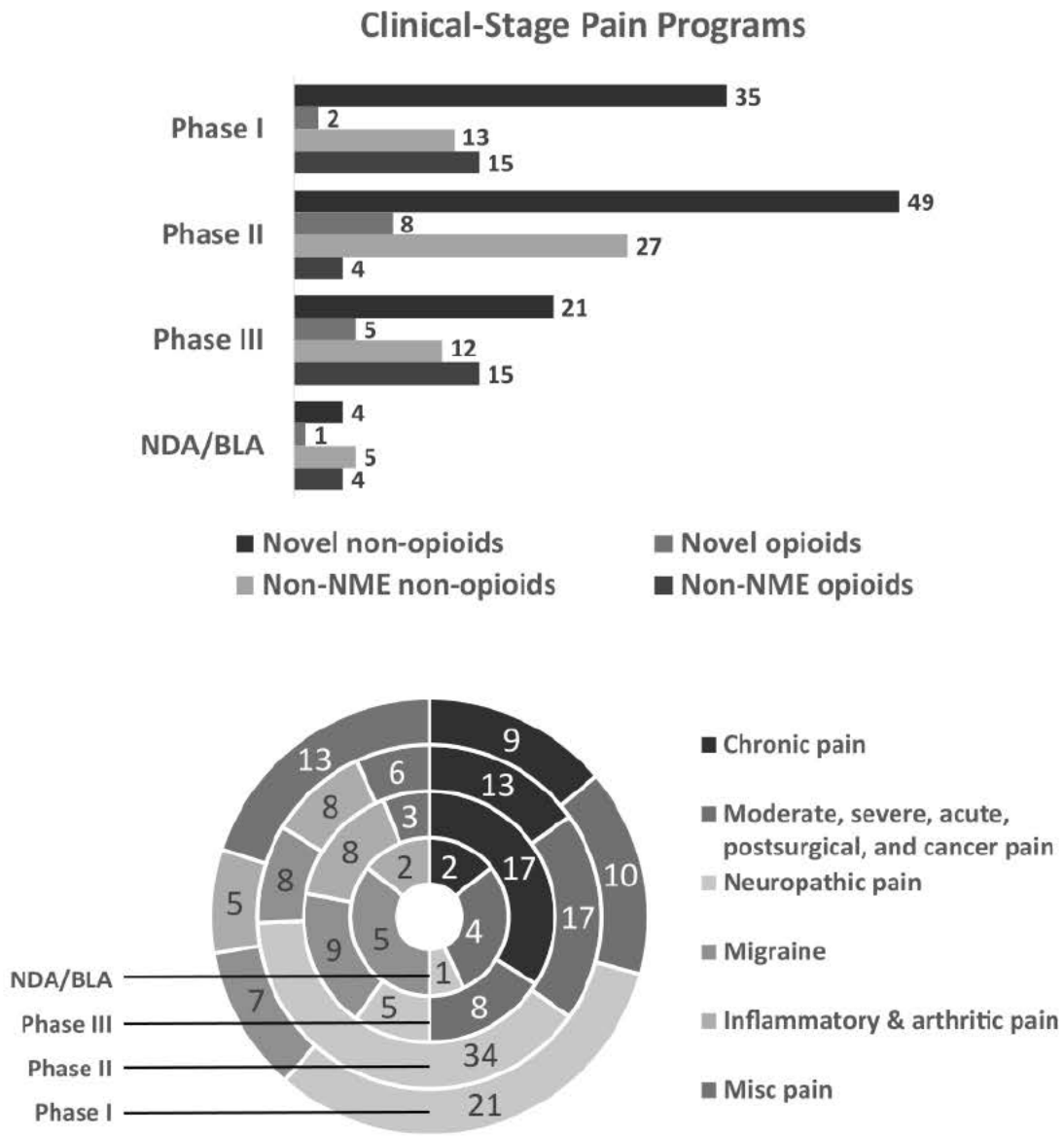

Figure 3. The currently active pain pipeline, based on Biomedtracker's methodology. Top: Pain pipeline by phase of development. Novel drugs that do not have an approval history, non-NME drugs that are reformulated or repurposed products, and each group split by opioid receptor activity. For combination drugs, only the novel active component is used to categorize as novel. If no novel compound is present in the combination drug, the Non-NME label is used. Bottom: Radar plot by earliest (outer) to latest phase (center) and by type of pain. Biomedtracker indications for chronic pain, and chronic lower back pain are combined, postsurgical pain, and moderate to severe pain, acute and cancer pain were combined. Neuropathic pain includes general neuropathic pain along with Biomedtracker indications for neuropathies, neuralgia, sciatica, and fibromyalgia. Migraine and other headaches are grouped separately. Misc pain includes many phase I programs that are not specified as to the type of pain, and a few local anesthetics.

NIH - 004496

The current clinical programs in pain can be grouped into 26 mechanistic strategies. These strategies' targets are different than previously discussed (FDA approved) mechanistic strategies. Among these 26 strategies, there are new enzyme and receptor targets modulated by small molecules, neuropeptides inhibited by antibodies, and cell-based approaches, under investigation for pain.

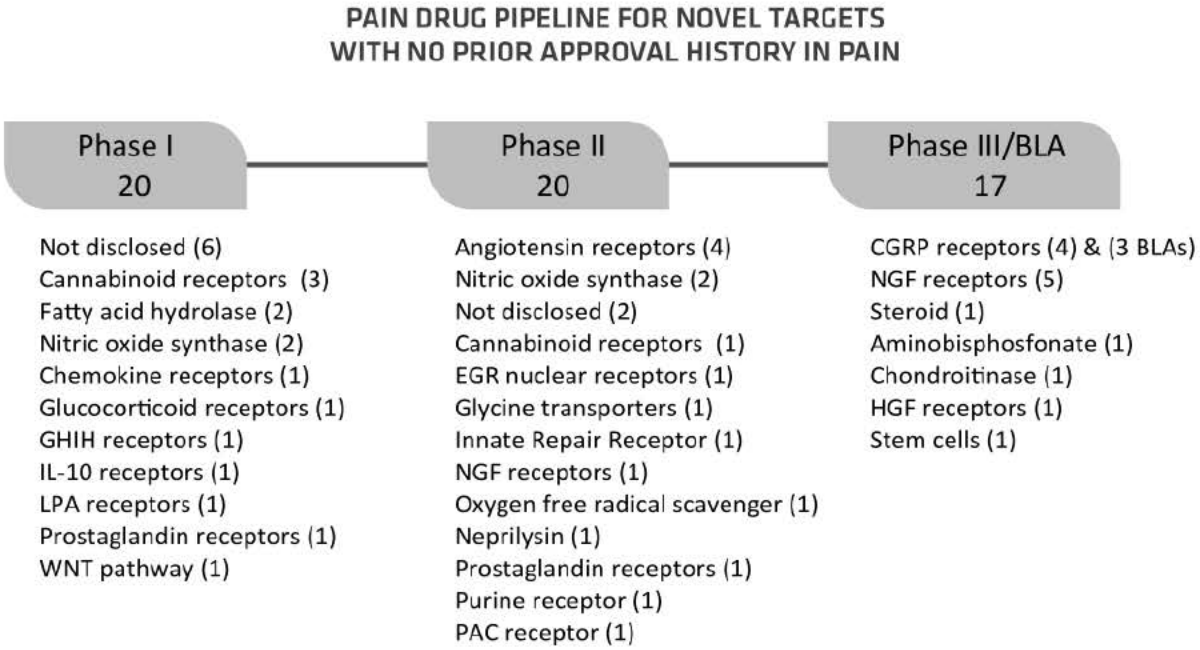

Figure 4. The breadth of completely new target strategies in the currently pain pipeline. The drug targeting strategy listed is based on the primary target of the novel compound under development. For combination drugs, only the novel active component's target is listed. Pipeline data by phase of development was obtained from Biomedtracker.

The 17 novel Phase III and NDA/BLA candidates listed in **Figure 4** are spread across seven mechanistic strategies. Furthest along, with three BLAs filed with the FDA in 2017, are the calcitonin gene-related peptide (CRGP) antibodies. This peptide is implicated in pain transmission through vasodilation and other physiological roles. The antibodies bind CRGP, rendering it unable to impact downstream activity. Nerve growth factor (NGF) antibodies are also represented, with 5 Phase III trials ongoing. NGF is a large neuropeptide involved in the maintenance of sensory neurons. Phase III programs also include representative candidates including the use of hepatocyte growth factor, chondroitinase, bisphosphonates, steroids, and stem cells.

However, when compared to the level of innovation occurring in other diseases, the need for greater investment in pain research and development is clear. For comparison, the oncology pipeline currently has 2,671 total active clinical programs, more than 10 times the number found in the pain pipeline (220).[14] The number of clinical programs in a single oncology sub-indication is closer to that found in the pain pipeline. For example, breast cancer has 158 active clinical development programs, lung cancer 180, and leukemias 211 – each slightly below the total pain pipeline. However, when we compare the number of *novel* drugs only (new molecular entities and new biologics), the novel pain pipeline consists of fewer programs: breast cancer (n=137), lung cancer (n=168), and leukemias (n=200) vs. pain (n=125).

To predict what may enter the clinical pipeline in the near future, we examined all preclinical pain programs in the Biomedtracker and EvaluatePharma databases. We found that 13 of the 59 preclinical programs listed had drugs for unique targets not currently in the clinic or previously approved, indicating further advances may be on the horizon.

[14] Data for oncology R&D pipeline is taken from the BioMedTracker database, and current as of January 2018. A total count by disease area can be found in Thomas, D., Wessel, C. Emerging Company Trend Report, BIO Industry Analysis (2017) (www.bio.org/iareports)

NIH - 004497

Trends in Venture Investment and R&D Activity (Clinical Trial Initiations) in Pain

Uncovering the exact dollar amounts that private and public companies are spending on pain drug development has limitations. Nevertheless, we have outlined below a few methods of approximating the level of private company venture capital investment (emerging, non-public biotech companies) and the broader industry R&D activity (combining small, midsize, and large public companies and private biopharmaceutical companies). For small private companies, we identify companies with lead compounds in pain and assess venture funding over time. This tends to underestimate the venture dollars ultimately used for pain R&D in small companies, as some companies have broad pipelines. Although most capital will tend to be used for the lead asset, this is not always the case. A more comprehensive method for assessing investment across the industry is based on quantifying the number of clinical trials starts by phase over time.

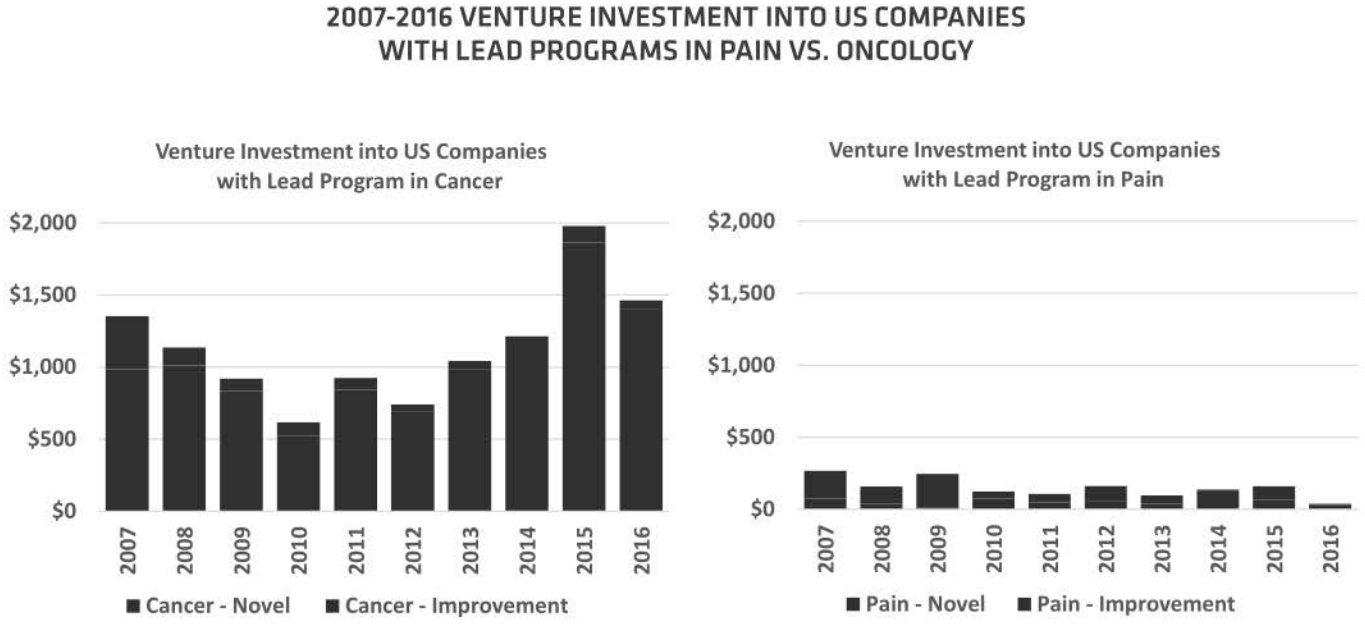

Figure 5. Left: Venture funding of companies with lead products in oncology, 2007-2016. Right: Venture funding of companies with lead products in pain, 2007-2016. Blue bars denote novel drug in lead program of company. Red bars indicate drug improvement (reformulation, repurposing) for the lead asset under development.

Venture investment into US companies with lead pain products from 2007 to 2016 totaled $1.5 billion. Using the "lead product" method for tracking venture investment, we also assessed whether the funded company was developing "drug improvement" reformulations or truly novel drug candidates. The funding for all novel pain drugs was only $576 million over the ten-year window, which is 17 times less than the funding received for novel oncology drugs ($10.3 billion). During the period from 2007 to 2016, six companies with lead drugs in pain were financed each year, on average. By comparison, there were 68 oncology companies financed each year, suggesting that early-stage investors currently prioritize other disease areas, such as oncology, over pain.

2006-2016 CLINICAL TRIAL STARTS FOR PAIN INTERVENTION TRIALS FOR PAIN

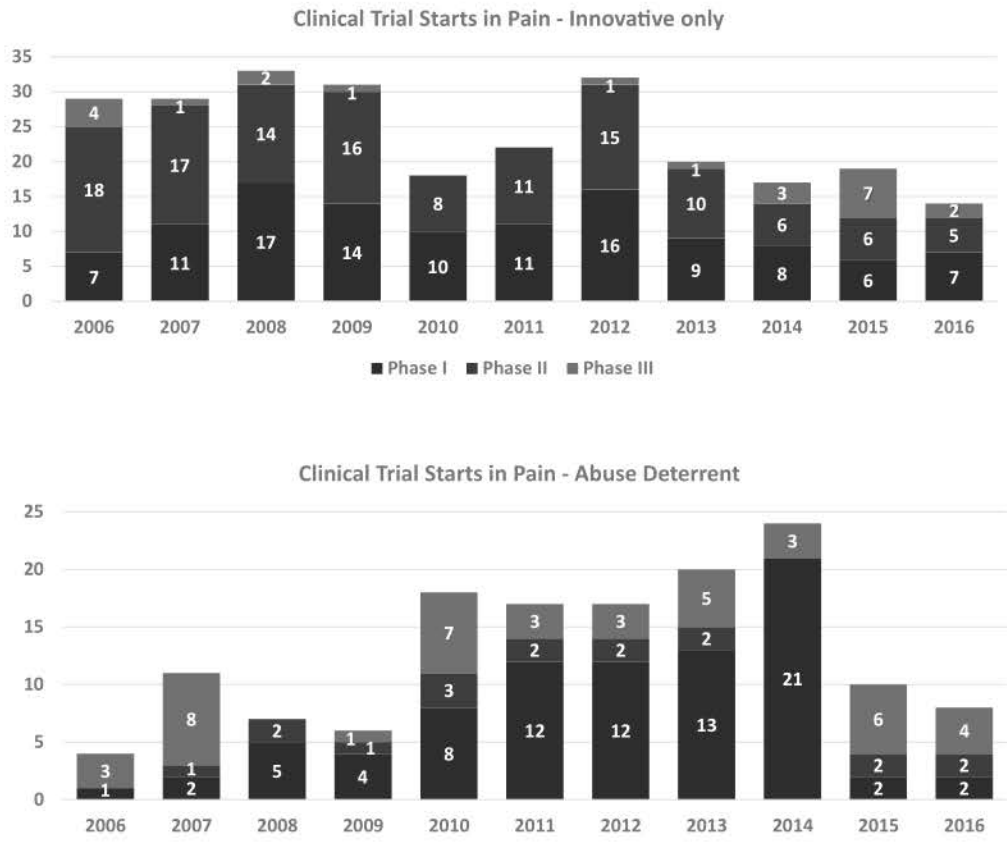

Figure 6. Clinical trial starts for Pain, 2006-2016. TrialTrove data accessed November 2017. Top: total of 1,930 clinical trial starts were retrieved from TrialTrove (on November 2017). Top: Trials were individually assessed for novelty of drug (no prior approval history of the active compound) and trial phase cohorts de-duplicated. A total of 290 novel drug intervention trials were initiated. Bottom: Trials were individually assessed for physical modification into abuse deterrent formulations of previously approved opioids, and all trial starts counted by year.

Looking at clinical trial starts over the last decade shows a more robust interest in pain. **Figure 6** shows the results from our analysis of TrialTrove data, where we individually assessed 1,950 clinical trials launched since 2006 for novelty of drug (no prior approval history of the active compound) and trial phase cohorts removed to avoid double counting. A total of 290 novel drug intervention trials were initiated between 2006 and 2016. However, we found clinical trial initiations (based on our analysis) declined 25% in the recent five-year period (2012-2016, n=111) compared to the prior five-year period (2007-2011, n=149). Phase III trial starts have totaled fewer than four per year in every year since 2006, with the exception of 2015. (The increase in 2014-2015 is attributable to the anti-CRGP migraine trials.) The low numbers of Phase III trial starts will be addressed in the following section on clinical trial success rates.

Trials were also individually assessed for physical modification into abuse deterrent formulations (ADFs) of previously approved opioids, and all trial starts counted by year. We observed a total of 142 ADF trials initiated since 2006, with a large increase over the 2010-2014 timeframe, perhaps coinciding with reports of additional unmet need in the opioid area. Although the majority were Phase I starts, there were 43 Phase III trials initiated during this period. There has been progress made in reformulating approved opioids into abuse deterrent versions as seen by the increased clinical activity in 2010-2014 and the 12 ADFs for six different opioids (morphine, oxycodone, oxymorphone, fentanyl, tapentadol, and tramadol) approved recently.

Based on our analysis of venture investment in small biotechnology companies and the number of clinical trials starts data (which includes public companies, large and small), publicly traded companies appear more active in the development of pain medications than small privately held companies.

NIH - 004499

Clinical Development Success Rates for Novel Pain Drugs

Evidence of the drought in new products for treating pain can be understood when the staggering degree of failure of clinical programs is considered over the last decade. Looking at new molecular entities in pain, we found one of the highest clinical trial failure rates of any major disease category.[15] As shown in **Figure 3**, novel pain drug development programs in Phase II had only a 16% chance of success in transitioning to Phase III, and only a 39% chance of transitioning from Phase III to NDA filing. These high Phase II and Phase III failure rates were a major contributor to the low overall probability of success (only 2.0%) for drug programs moving from Phase I all the way to FDA approval, compared to 9.6% across all disease areas.[16]

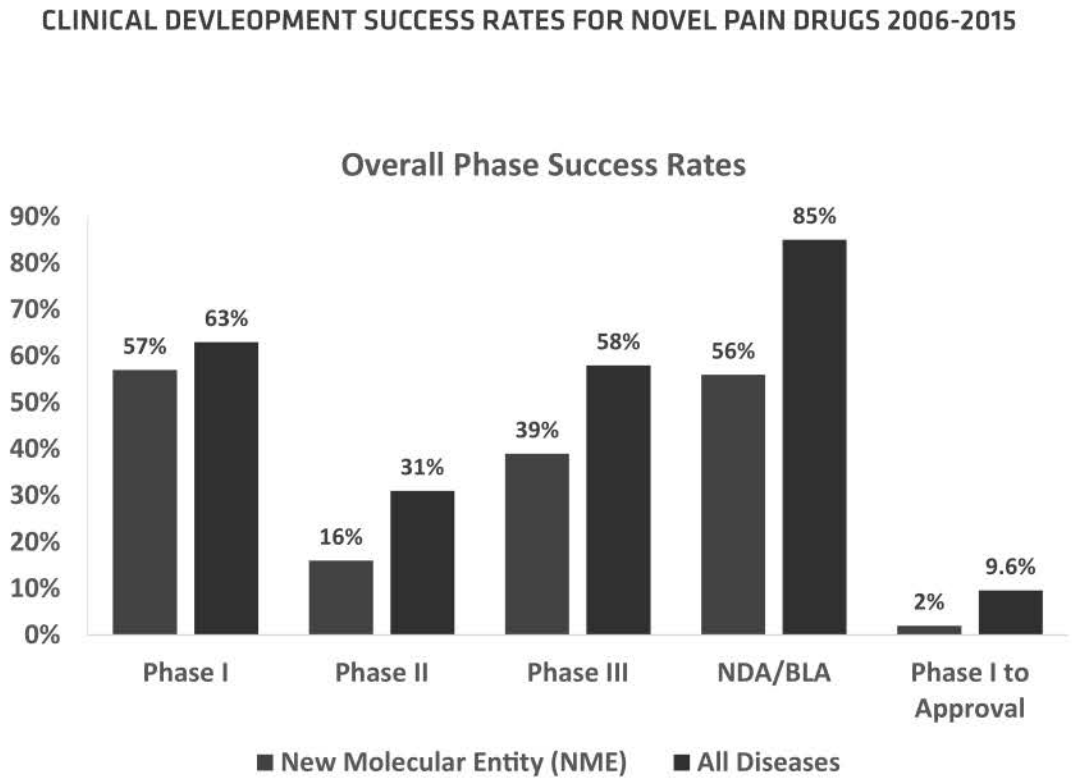

Figure 7. Clinical success rates for all Pain indications compared to overall industry probabilities, 2006-2015. Data is based on approximately 10,000 drug programs in the Biomedtracker database. (Thomas, D., et al. BIO, BioMedtracker, Amplion. Clinical Development Success Rates 2006-2015 (2016) (Accessed at www.bio.org/iareports)

Analyzing the R&D programs that were active in the period 2006-2017, we found that 183 clinical programs targeting new targets are now suspended. Examples of failed strategies are numerous and include targets such as the NK-1 receptor, p38 MAP kinase, AMPA glutamate receptor, metabotropic glutamate receptor (mGlu5), histamine H3 receptor, mitochondrial peripheral benzodiazepine receptor (PBR), and collapsin response mediator protein 2 (CRMP-2). The current pipeline includes novel chemical structures and modalities directed at targets that have experienced failure in the past. This reflects scientific advancement based on learned experiences and have the potential for success. For example, the Nerve Growth Factor (NGF) target has seen 12 failed programs but has six active novel clinical development programs.[17]

[15] Thomas, D., et al. BIO, BioMedtracker, Amplion. Clinical Development Success Rates 2006-2015 (2016) (www.bio.org/iareports)

[16] The low success rate for novel drugs was not observed for the non-NME pain drugs (those that are mostly reformulations of older APIs). The non-NME drugs had an overall 25% success rate.

[17] Other ongoing programs with a prior history of failure include cannabinoid receptors (CB1 and CB2), chemokine receptors, vanilloid receptor TRPV1, fatty acid hydrolases, and the receptor for CRGP.

NIH - 004500

Overview of FDA Approved Addiction Therapeutics

According to sources compiled by the NIH Institute of Drug Abuse, the abuse of tobacco, alcohol, and other drugs is costing the US more than $740 billion annually in costs related to healthcare, lost work productivity, and crime. In terms of direct healthcare costs, tobacco remains at the top of the list ($168 billion, 2010), followed by opioid abuse ($28.5 billion, 2013) and alcohol abuse ($27 billion, 2010).[18] This report examines currently available therapeutic options and the current pipeline for substance use disorders (including opioids, alcohol, nicotine, stimulants, and cannabis).

UNIQUE CHEMICAL ENTITIES FDA APPROVED FOR ADDICTION

Addiction Type	Unique Chemical Entities (Examples)	Mechanistic Strategy
Opioid Use Disorder	naltrexone (Trexan, Vivitrol)	opioid receptor antagonist (competitive to opioid agonists drugs
	naloxone (in combination with buprenorphine) (Bunavail, Zubsolv, Suboxone)	opioid receptor antagonist (competitive to opioid agonists drugs
	buprenorphine (Subutex, Probuphine, Sublocade)	opioid receptor modulation (partial agonist)
	methadone (Dolophine)	opioid receptor agonist and nicotinic acetylcholine receptor antagonist
Alcohol Use Disorder	naltrexone (Revia, Vivitrol)	opioid receptor antagonist (competitive to opioid agonists drugs
	disulfiram (Antabuse)	alcohol dehydrogenase inhibition
	acamprosate (Campral), and benzodiapines* (diazepam (Valium), oxazepam, clorazepate (Tranxene), chlordiazepoxide (Librium))	GABA receptor modulation
Nicotine Use Disorder	bupropion (Zyban)	monoamine modulation
	varenicline (Chantix)	nicotinic acetylcholine receptor partial agonist
	nicotine (as patch)	nicotinic acetylcholine receptor agonist
Stimulant Use Disorder	no approvals (i.e. for cocaine, methamphetamine)	
Cannabis Use Disorders	no approvals	

* prescribed only for symptoms of withdrawal (tremors, anxiety), for example clorazepate, oxazepam

Figure 8. Unique FDA approved active ingredients for addiction, marketed in the US as of January 2018 (prescription, generic, or OTC) categorized by primary mechanistic target strategy and physiological strategy. Under substance abuse, the FDA approved drug levomethadyl (OrLAAM) is omitted as the patent holding manufacturer as discontinued sale of the product. See text for details. *Benzodiazapines are prescribed for symptoms of withdrawal (tremors, anxiety), for example clorazepate, oxazepam (Source: EvaluatePharma, Biomedtracker, fda.gov, company websites.)

[18] https://www.drugabuse.gov/related-topics/trends-statistics#supplemental-references-for-economic-costs, accessed January 2018. References cited: U.S. Department of Health and Human Services. The Health Consequences of Smoking—50 Years of Progress. A Report of the Surgeon General. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health; 2014. Xu, X. et.al. Annual Healthcare Spending Attributable to Cigarette Smoking: An Update. American Journal of Preventive Medicine 2014;48(3):326–33. Centers for Disease Control and Prevention. Excessive Drinking is Draining the U.S. Economy. National Drug Intelligence Center. National Drug Threat Assessment. Washington, DC: United States Department of Justice; 2011. Birnbaum, HG. et al. Societal Costs of Prescription Opioid Abuse, Dependence, and Misuse in the United States. Pain Medicine 2011; 12: 657-667. Florence, C et al. The Economic Burden of Prescription Opioid Overdose, Abuse, and Dependence in the United States, 2013; Medical Care. Volume 54, Number 10, October 2016. (2004)

NIH - 004501

Drugs for Opioid Abuse Disorder

Currently available treatments for substance abuse disorder are all based on modulation of the opioid receptor, either antagonistically or agonistically but with different magnitude or effect compared to opioids used to treat pain. **Figure 8** lists the four active unique substances.

Naloxone: In 1971, the FDA approved naloxone (Narcan) for treating opioid overdose. Naloxone, a competitive opioid receptor antagonist, can work within minutes to block the effects of opioid overdose by competing for the same mu opioid receptors that opioids bind to, but act to decrease activity rather than increase activity. However, naloxone can also cause symptoms of withdrawal. It is now commonly prescribed as an oral drug in combination with buprenorphine such that the oral opioid is active, but any misuse by injection will be blocked.[19]

Methadone: Termed a replacement or maintenance therapy for its ability to help individuals taper their use of other opioids, methadone is a mu opioid receptor agonist. Methadone, already approved in 1947 for pain relief, was approved in 1972 for treating opioid abuse and to help with the growing abuse of street heroin.

Naltrexone: The 1972 Drug Abuse Office and Treatment Act called for the development of non-addictive "blocking or antagonistic drugs" and "detoxification agents" that could be used to treat withdrawal in the case of heroin addiction. It was not until 1984 that a new, strong antagonist to the opioid receptors was approved for heroin addiction. That drug was naltrexone, a potent antagonist of the mu opioid receptor. In 1995, it was approved for alcohol addiction. The original formulations of naltrexone required daily dosing, which raised issues with patient compliance. The more recent once-monthly formulation of naltrexone, Vivitrol, was approved in 2010 for opioid addiction.

Buprenoprhine: As a partial agonist at the mu opioid receptor, buprenoprhine works as a pain reliever and as a replacement or maintenance therapy for opioid addiction. It was originally approved as a standalone therapy in 1981 by the FDA, but is often used in combination with naltrexone.

Levacetylmethadol: Levacetylmethadol (not listed in **Figure 8**) was discontinued by the manufacturer based on evidence of cardiac-related side effects and the FDA's addition of new label warnings.[20] In 1993, OrLAAM, levomethadyl acetate, a structurally similar compound to methadone, was approved for opioid addiction in cases where methadone and buprenorphine have not proven effective.

Drugs for Alcohol Abuse Disorder

Only three classes of drugs are available for treating alcohol use disorder, working through three different mechanisms as categorized in **Figure 8**.

Disulfiram: Disulfiram is the oldest drug on the list in **Figure 8**, approved in 1951. This drug inhibits the enzyme that normally breaks down alcohol, creating a sensitivity to alcohol such that, when drinking, immediate hangover symptoms and unwanted side effects arise, making it unfavorable to continue consuming alcohol.

Naltrexone: As mentioned above, Naltrexone was originally approved in 1995 for treating alcohol dependence. The long acting version was approved in 2006.

Benzodiazepines: Four benzodiazepines have also been approved for use in the alcohol addiction setting. These work as a substitute for alcohol to help during the withdrawal stages as benzodiazepines work similarly to alcohol modulating GABA transmission.

[19] Orman, J. et. al. Buprenorphine/naloxone: a review of its use in the treatment of opioid dependence. Drugs. 69 (5): 577–607 (2009)

[20] FDA documents: https://www.federalregister.gov/documents/2011/06/06/2011-13884/determination-that-orlaam-levomethadyl-acetate-hydrochloride-oral-solution-10-milligramsmilliliter

Drugs for Nicotine Addiction

Nicotine & varenicline: For nicotine addiction, nicotine itself has been used since the 1980s in patch or gum form to help addicts alter their smoking habit. Nicotine and the key ingredient of Chantix (varenicline) work by activating what is now known as the "nicotine receptor" (nicotinic acetylcholine receptor) in the brain. This in turn causes the release of several brain chemical messengers, including dopamine, which contribute to the addictive properties of nicotine.

Bupropion: Bupropion, originally approved for depression (as Wellbutrin in the 1980s), was approved in 1997 for smoking cessation (renamed Zyban for this indication). Bupropion is known to decrease appetite cravings and elevate dopamine levels but may have other relevant activity such as antagonizing acetylcholine receptors.[21]

Current Clinical Pipeline for Addiction Therapeutics

There are 29 programs in the substance abuse disorder pipeline according to data obtained from the Biomedtracker database. As shown in **Figure 9**, the majority (18) are for treatment of opioid, stimulant, or cannabis addiction, five are for alcohol abuse disorders, and three are for smoking cessation and nicotine addiction. Breaking this pipeline into novel programs (new molecular entity small molecule, new biologic, or new vaccine) reveals only 15 novel ongoing clinical programs (five are broadly defined for treatment of substance abuse disorders, five are specific for cocaine, methamphetamine, or THC, two are for alcohol, three are for nicotine/tobacco). There seems to be a lack of breadth and depth in today's addiction therapy pipeline. In contrast, consider pain's 125 or breast cancer's 137 novel investigational compounds, as mentioned previously.

The five novel drug programs indicated broadly for substance abuse disorders are all early-stage (in Phase I or II trials, not in Phase III trials) and cover five different strategies. Esketamine (a ketamine enantiomer), while also being developed for depression, is in Phase II for treatment of substance abuse disorders. Ketamine has a range of targets, including various glutamate receptors, opioid receptors, and ion channels.[22] A peroxisome proliferator-activated receptor (PPAR) gamma agonist in Phase II is being used both for substance abused disorders in general and specifically to treat nicotine addiction. There is one serotonin–norepinephrine–dopamine (SNDRI) reuptake inhibitor in Phase II, as well as one undisclosed product. The fifth program is a selective alcohol dehydrogenase 2 (ALDH2) inhibitor in Phase I that works to stop addictive cravings due to dopamine surges.[23]

The five novel drug programs indicated for specific drugs in the addiction setting fall into two broad groups. First, there are three programs in early clinical development that use therapeutic agents to inactivate abused drugs. These drugs act either directly, for methamphetamine (using an antibody that binds meth) and cocaine (using an enzyme that inactivates cocaine), or indirectly, by recruiting the immune system to recognize and destroy the illicit substance. The two other abuse-specific programs are the cannabinoid receptor antagonists being developed for marijuana abuse.

For alcohol abuse, three early-stage drugs are listed as novel. Two of these drugs are prodrugs of active substances used in the pain setting.[24] A prodrug to gabapentin (a derivative of gamma-aminobutyric acid (GABA), recently approved for moderate-to-severe restless legs syndrome and postherpetic neuralgia), reduces calcium channel activity and enhances GABA like effects. A prodrug of baclofen, also a derivative of GABA, is in phase II. An intranasal formulation of Naltrexone is also under development.

For nicotine addiction, there are three very distinct agents under development. First, cytisine is in early-stage clinical trials. It is believed to act similarly to varenicline (in **Figure 8**) as a partial agonist of nicotinic acetylcholine receptors. As mentioned above under substance abuse, a peroxisome proliferator-activated receptor (PPAR) gamma agonist is being tested for nicotine addiction. Lastly, a conjugate vaccine program against nicotine has been in clinical trials for well over a decade.

The 12 non-NME drugs in the addiction pipeline include three combination drugs and nine reformulations of approved drugs. It is important to note that some of these products are being tested in addiction indications for the first time, or are being developed into formulations or delivery systems that will increase patient compliance.

[21] Roddy, E. Bupropion and other non-nicotine pharmacotherapies. BMJ, 328 (7438): 509–511. (2004)
[22] Sleigh, J., et al. Ketamine – More mechanisms of action than just NMDA blockade. Trends in Anaesthesia and Critical Care, 4 (2-3): 76-81 (2014)
[23] Phase of product and target information in this section are based on Biomedtracker and company websites accessed January 2018.
[24] Prodrugs are drugs inactive until the body metabolizes them into the active chemical entity.

NIH - 004503

R&D Investment for Addiction Therapeutics

Venture investment into US companies with lead products in addiction has been virtually nonexistent over the past 10 years. Although using the "lead product only" methodology underestimates investment, as it only takes into account lead program disease indication, the picture is nonetheless bleak. We only identified $16 million invested across two addiction-focused companies over the last decade. Furthermore, both companies had lead products for alcohol dependence, not substance abuse. Assessing clinical trial starts in this area was not possible due to the lack of defined indication tagging for these three specific indications in Trialtrove. Thus, we were unable to assess R&D investment trends across the biopharmaceutical industry (emerging, mid and large biopharmaceutical companies as we did for our analysis of R&D activity for pain. However, based on our analysis of active clinical trial programs it is fair to assume it has not been substantial.

Due to the low number of active clinical programs over the past decade, it was not prudent to calculate success rates for addiction drug development using Biomedtracker data. However, suspended programs listed in the Biomedtracker database include eight for substance abuse, 12 for nicotine addiction (smoking cessation), and 14 for alcohol abuse. As suspended programs (38) outnumber ongoing programs (29), and not a single novel chemical entity has been approved in more than a decade, evidence suggests a low rate of success in this area.

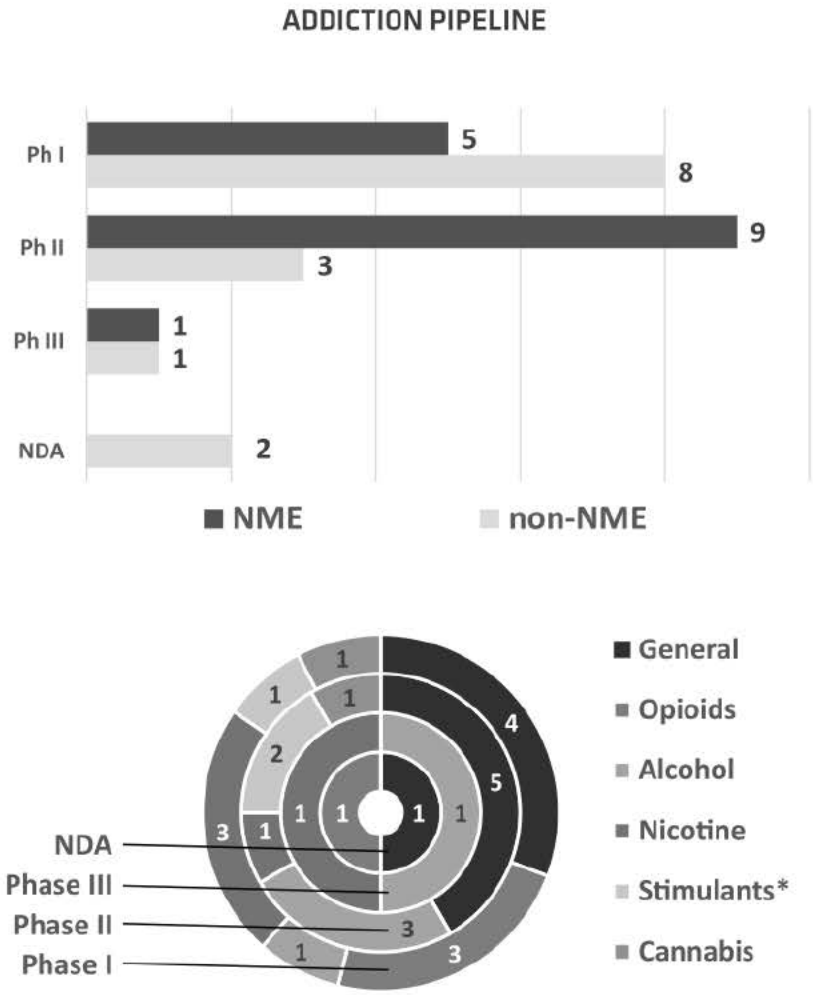

Figure 9. The addiction pipeline, based on Biomedtracker database, January 2018. Top: Addiction pipeline by phase of development and by novelty criteria: Novel drugs that do not have an approval history and non-NME drugs that are reformulated or repurposed products. For combination drugs, only the novel active component is used to categorize as novel. If no novel compound is present in the combination drug, the "Non-NME" label is used. Bottom: Radar plot by earliest (outer) to latest phase (center) and by type of addiction. Geenral addiction includes many phase I programs that are not specified as to the type of addiction, as well as others that are designed to treat a variety of addiction disorders. *Stimulants only includes cocaine and methamphetamine.

NIH - 004504

Discussion

With 125 novel drug programs in the clinic to treat pain, there is potential for innovation to change how pain is treated through alternatives to current therapies. Recent innovative formulations of approved active substances have also led to safer pain medicines, with 12 ADFs approved in the last decade and a clinical pipeline of 95 non-NME programs progressing. The status of innovation in addiction treatments is very limited, with only 15 novel programs making their way through the clinic (only five of which might be applicable to opioid abuse).

When examining the current state of unmet need and public health burdens caused by both pain and addiction, policies that support an improved scientific understanding of the neurobiology of pain and addiction will allow for better identification of novel targets, while policies supporting efficient and effective regulatory environments and coverage for treatments in this area will provide more therapeutic options for patients with pain and addiction.

Advancing our understanding of the biology of pain and addiction and encouraging modern approaches to drug development and coverage would stimulate investment and novel R&D activity in these disease areas. For example, developing animal models that are better able to predict safety and efficacy in humans, biomarkers that could be used to stratify patient populations, development and utilization of modern approaches for diagnoses and drug development, and unleashing the power of data to better predict what treatments work best and for whom would all serve to incentivize innovation and change the paradigm of how we treat pain and addiction.

Additionally, barriers to access to and coverage of innovative medicines have a strong negative impact on investment. This can be a significant factor in disease areas where generic drugs are the predominantly prescribed medicines even when there are very large patient populations to treat. There are potentially 100 million people currently experiencing some form of chronic pain in the US and more than 90% of the prescribed medicines for pain have a generic option available. Recent drug launches in chronic, highly prevalent indications, even launches of highly innovative drugs, have faced challenges to coverage and access, creating uncertainty in the investor community.

The Biotechnology Innovation Organization (BIO) and member companies view innovation as the key to changing the paradigm for the treatment of pain and addiction. Advancements in science, more choices for patients, and a policy environment that stimulates investment in R&D are necessary to achieve this goal. (Please visit www.bio.org/opioid for more information).

NIH - 004505

Bio Industry Analysis

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Acknowledgements

We would like to acknowledge Cartier Esham, Danielle Friend, and Charles Crain for their review of this report.

Cover photo by Science Health (https://www.flickr.com/photos/42750848@N02/6461022819)

NIH - 004506

From: Wholley, David (FNIH) [T]
Sent: Tue, 13 Feb 2018 20:28:42 +0000
To: Collins, Francis (NIH/OD) [E]
Subject: IOM Neuroscience Forum

Hi Francis – the meeting is on March 5, and the note from Clare Stoudt at IOM characterized the agenda item as:

- Continue discussion on advancing therapeutic development for pain and opioid use disorders through public-private partnerships and related initiatives, and identify any next steps for the Forum.

David Wholley
Director, Research Partnerships
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2017 Gold Stevie Award Winner for Organization of the Year

From: Wholley, David (FNIH) [T]
Sent: Fri, 2 Feb 2018 18:56:52 +0000
To: Baker, Rebecca (NIH/OD) [E];Collins, Francis (NIH/OD) [E]
Cc: Biarnes, Michael (FNIH) [T];Menetski, Joseph (FNIH) [T];Tabak, Lawrence (NIH/OD) [E];Wolinetz, Carrie (NIH/OD) [E];Collins, Francis (NIH/OD) [E]
Subject: Re: Opioid White Paper First Draft Master Jan 27

Thanks, Rebecca. We will consider both of your suggestions and look at the changes. It will be important to try to accomodate everyone without having to reconvene co-chairs, not to mention working groups however. I trust NIH agrees with that sentiment.
FYI I am expecting feedback from FDA as well, likely by cob today I am told. We look forward to your changes on the governance sections as well.
Sent from my BlackBerry 10 smartphone.

From: Baker, Rebecca (NIH/OD) [E]
Sent: Friday, February 2, 2018 1:47 PM
To: Collins, Francis (NIH/OD) [E]; Wholley, David (FNIH) [T]
Cc: Biarnes, Michael (FNIH) [T]; Menetski, Joseph (FNIH) [T]; Tabak, Lawrence (NIH/OD) [E]; Wolinetz, Carrie (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]
Subject: RE: Opioid White Paper First Draft Master Jan 27

Hi David and team,

Thanks again for the opportunity to review the white paper, and for the amazing effort to pull it together in such a short time-frame.

As discussed yesterday, and in the interest of integrating the specific edits suggested by NIH, I've attached a combined revised version. Given our shared concerns with the governance sections, though, we'll consult internally and come back with a proposed middle-ground solution. This might require more time to resolve.

Please also note two high level suggestions below:

Please let me know if you have any questions or if we can help at all in further revisions.

Thanks,

Rebecca

From: Collins, Francis (NIH/OD) [E]
Sent: Sunday, January 28, 2018 6:27 PM
To: Wholley, David (FNIH) [T] <dwholley@fnih.org>
Cc: Biarnes, Michael (FNIH) [T] <mbiarnes@fnih.org>; Menetski, Joseph (FNIH) [T] <jmenetski@fnih.org>; Tabak, Lawrence (NIH/OD) [E] (b) (6); Baker, Rebecca (NIH/OD) [E] (b) (6); Wolinetz, Carrie (NIH/OD) [E] (b) (6)
Subject: RE: Opioid White Paper First Draft Master Jan 27

Hi David et al.,

I had the chance to scan through the White Paper on the return trip from Davos. In general, this looks really well done – compelling presentation of scientific opportunities and how they can be tackled by the partnership. I really like how the OUD and pain components are melded together.

I made a few edits on the document, but didn't try to be very detailed. See attached.

(b) (5)

FC

From: Wholley, David (FNIH) [T]
Sent: Saturday, January 27, 2018 7:51 PM
To: Baker, Rebecca (NIH/OD) [E] (b) (6)
Cc: Collins, Francis (NIH/OD) [E] (b) (6); Biarnes, Michael (FNIH) [T] <mbiarnes@fnih.org>; Menetski, Joseph (FNIH) [T] <jmenetski@fnih.org>
Subject: Opioid White Paper First Draft Master Jan 27
Importance: High

Rebecca, here is the first draft of the Opioids Partnership White Paper to take through NIH review. It contains everything except the Executive Summary, which we are working on in parallel (and essentially will just repeat what is in the document, compressed into two pages). We'll send that along separately when it is finished.

It's a big document, and final edits took us all day, so I apologize we were not able to get it out this morning.

Francis asked for an early look in our last NIH opioid team meeting, and given the lateness of the hour, I am copying him directly on this as well. Please send edits to me and Mike Biarnes and copy Joe Menetski at your earliest convenience. Rich M. has still asked for something on Feb. 1 so it can be sent to the CEOs in time for the Feb. 7 meeting. FYI I am sending this now also to the co-chairs, to FDA, and to PhRMA as we agreed, for their initial edits.

Thanks for your patience

David

From: Wholley, David (FNIH) [T]
Sent: Tue, 13 Feb 2018 16:48:45 +0000
To: Collins, Francis (NIH/OD) [E]
Cc: Wood, Gretchen (NIH/OD) [E];Melencio, Cheryl (FNIH) [T]
Subject: RE: Update

Sure. Let me know how you'd like to connect.

From: Collins, Francis (NIH/OD) [E]
Sent: Tuesday, February 13, 2018 11:47 AM
To: Wholley, David (FNIH) [T] <dwholley@fnih.org>
Cc: Wood, Gretchen (NIH/OD) [E] (b) (6)
Subject: RE: Update

Sure. How about 3 PM today?

From: Wholley, David (FNIH) [T]
Sent: Tuesday, February 13, 2018 10:22 AM
To: Collins, Francis (NIH/OD) [E] (b) (6)
Subject: Update

Francis, I had a call from Rich Moscicki yesterday. Let me know if you want to chat. David

David Wholley
Director, Research Partnerships
Foundation for the National Institutes of Health
(301) 594-6343
fnih.org
11400 Rockville Pike Suite 600 North Bethesda, MD 20852

2017 Gold Stevie Award Winner for Organization of the Year

From: Wholley, David (FNIH) [T]
Sent: Tue, 13 Feb 2018 15:22:00 +0000
To: Collins, Francis (NIH/OD) [E]
Subject: Update

Francis, I had a call from Rich Moscicki yesterday. Let me know if you want to chat. David

David Wholley
Director, Research Partnerships
Foundation for the National Institutes of Health
(301) 594-6343
fnih.org
11400 Rockville Pike Suite 600 North Bethesda, MD 20852

2017 Gold Stevie Award Winner for Organization of the Year

From: Wholley, David (FNIH) [T]
Sent: Tue, 20 Feb 2018 22:33:08 +0000
To: Collins, Francis (NIH/OD) [E];Tabak, Lawrence (NIH/OD) [E];Hoffmann, Steve (FNIH) [T];Canet-Aviles, Rosa (FNIH) [T];Kamphaus, Tania (FNIH) [T];Gadbois, Ellen (NIH/OD) [E];Singh, Jyoti (NIH/OD) [E];Wood, Gretchen (NIH/OD) [E];Burrus-Shaw, Cyndi (NIH/OD) [E];NIHDirectorMeetings;McManus, Ayanna (NIH/OD) [E];Menetski, Joseph (FNIH) [T];Morgan, Emily (FNIH) [T];Vardanian, Lilit (FNIH) [V];Di Mantova, Emma (NIH/OD) [E]
Subject: AMP Executive Committee Pre-Call materials
Attachments: AMP EC Slides Feb 23- DRAFT.pptx, 2017_12_15_AMP EEC teleconference draft.docx, 2017_10_27_AMP EC teleconference draft.docx, AMP EC Feb 23 2018_Attendees.xlsx
Importance: High

Here are the slides for tomorrow morning's call, along with minutes from the last EEC and EC meetings, and a current projected attendance profile for Friday's EC call.

Thanks, David

Accelerating Medicines PartnershipExecutive Committee Update

23 February, 2018

FNIH
Foundation for the National Institutes of Health

Agenda

(b) (5)

(b) (4), (b) (5)

Accelerating Medicines PartnershipAlzheimer's Disease

FNIH

Foundation for the National Institutes of Health

NIH - 004517

(b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

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(b) (4), (b) (5)

Accelerating Medicines PartnershipType 2 Diabetes

FNIH

Foundation for the
National Institutes of Health

NIH - 004524

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(b) (4), (b) (5)

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Accelerating Medicines PartnershipParkinson's Disease

FNIH

Foundation for the
National Institutes of Health

NIH - 004534

(b) (4), (b) (5)

(b) (4), (b) (5)

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(b) (4), (b) (5)

AMP PD F2F Annual Meeting 2018

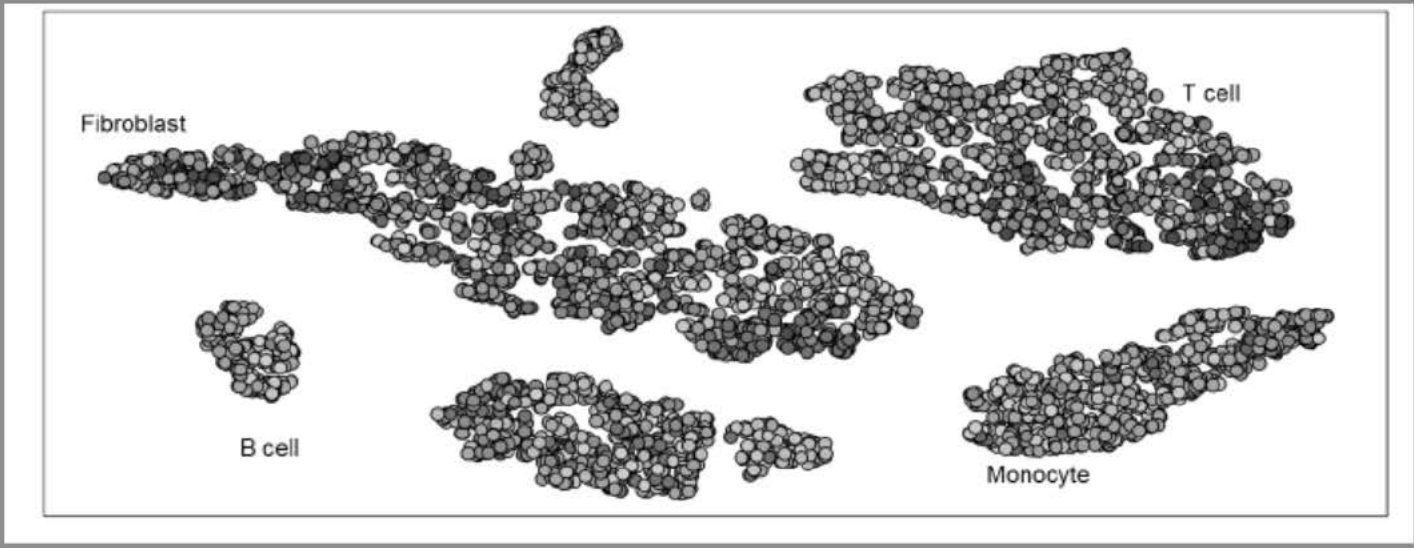
- (b) (5)

NIH - 004540

(b) (4), (b) (5)

(b) (4), (b) (5)

Accelerating Medicines PartnershipRA/SLE



FNIH

Foundation for the
National Institutes of Health

NIH - 004543

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(b) (4), (b) (5)

Upcoming EC meetings

- **Next MeetingAMP EC: Friday, April 27 from 7:00 am – 8:30 am**

NIH - 004551

Backup Slides

(b) (4), (b) (5)

(b) (4), (b) (5)

Foundation for the National Institutes of Health (FNIH)
Accelerating Medicines Partnership (AMP)
Extended Executive Committee (EEC)
Teleconference Meeting Minutes

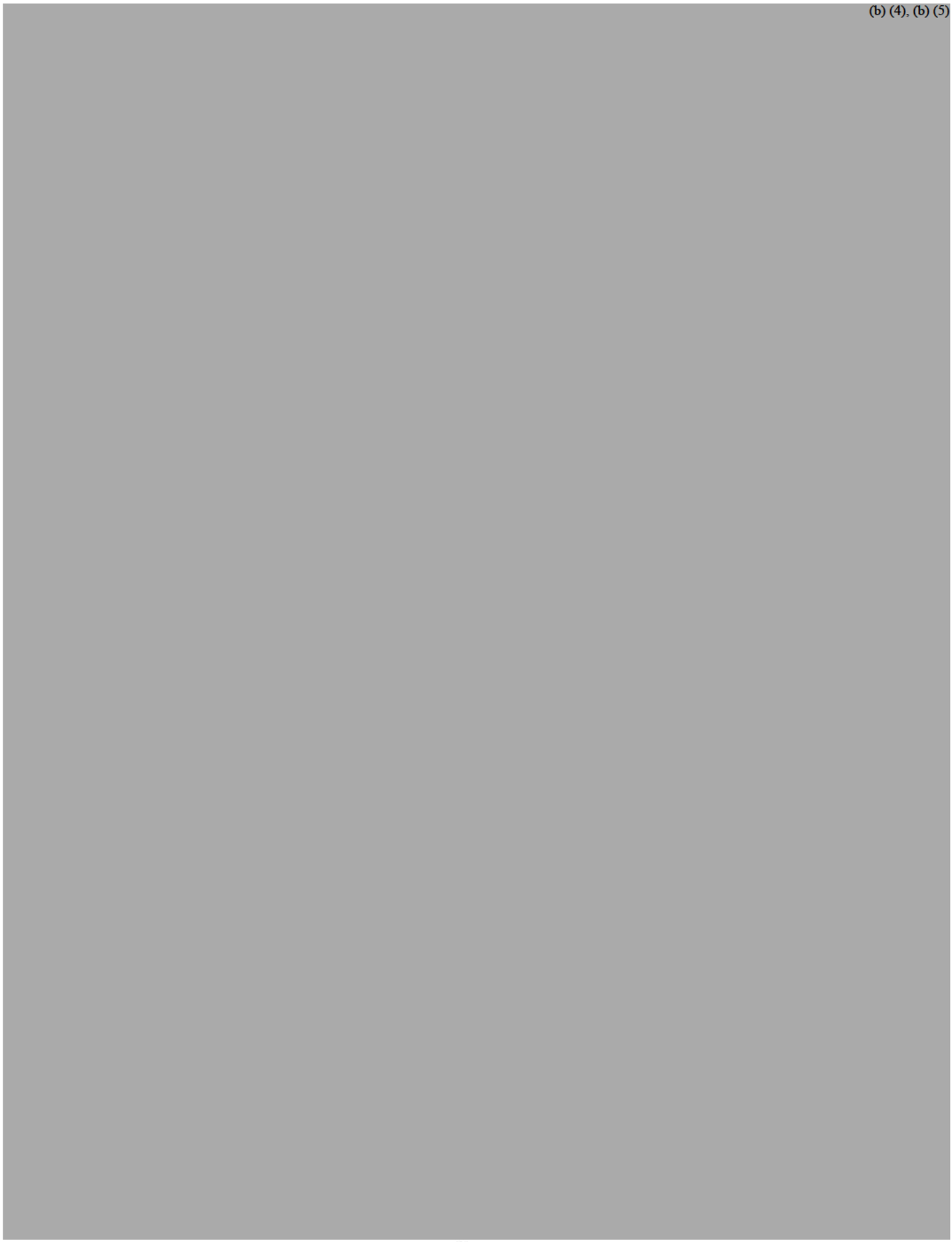
Friday, December 15, 2017
7:00 – 8:30 a.m. ET

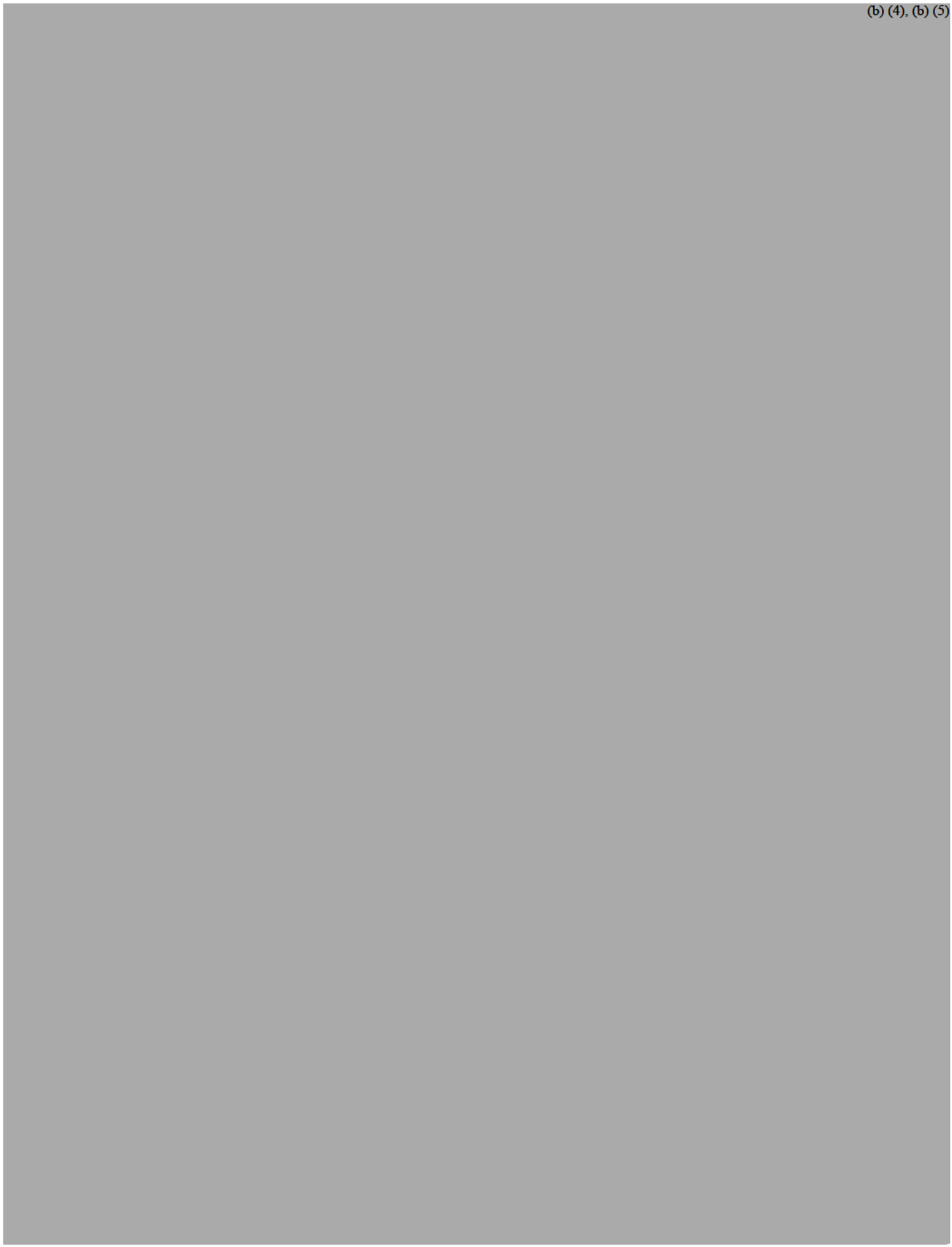
Participants

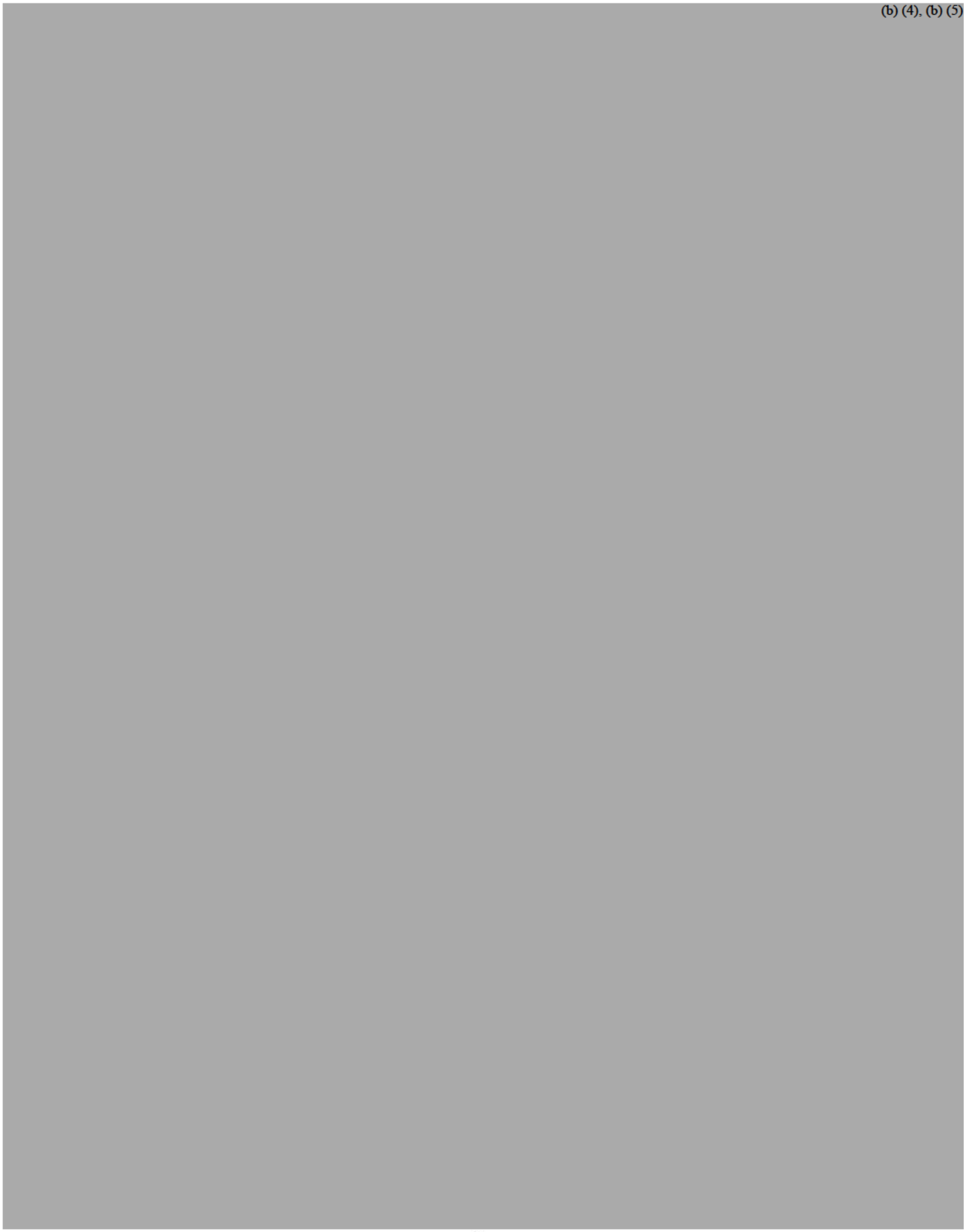
Rosa Canet-Avilés (FNIH), Bob Carter (NIH/NIAMS), Bill Chin (PhRMA), David Collier (Lilly), Francis Collins (NIH), Mary Collins (Lupus Research Alliance), Patrick Cullinan (Takeda), Mikael Dolsten (Pfizer), Guy Eakin (Arthritis Foundation), Tanya Fischer (Sanofi), Ellen Gadbois (NIH), Ellen Goldmuntz (NIH/NIAID), James Hendrix (Alzheimer's Association), Richard Hodes (NIH/NIA), Marty Hodge (Pfizer), Steve Hoffmann (FNIH), Tania Kamphaus (FNIH), Stephen Katz (NIH/NIAMS), Andrew Koemeter-Cox (Alzheimer's Drug Discovery Foundation), Walter Koroshetz (NIH/NINDS), Jan Lundberg (Lilly), Joe Menetski (FNIH), Joseph Miletich (Merck), Richard Moscicki (PhRMA), Dina Paltoo (NIH), Suzana Petanceska (NIH/NIA), Marlon Pragnell (JDRF), Griffin Rodgers (NIH/NIDDK), Daniel Rotrosen (NIH/NIAID), Laurie Ryan (NIH/NIA), Susana Serrate-Sztein (NIH/NIAMS), Todd Sherer (MJFF), Jyoti Singh (NIH), Phil Smith (NIH/NIDDK), Paul Stoffels (J&J), Marg Sutherland (NIH/NINDS), Terri Tarrant (Rheumatology Research Foundation), Melissa Thomas (Lilly), Lilit Vardanian (FNIH), David Wholley (FNIH), Janet Woodcock (FDA)

(b) (4), (b) (5)

[redacted]







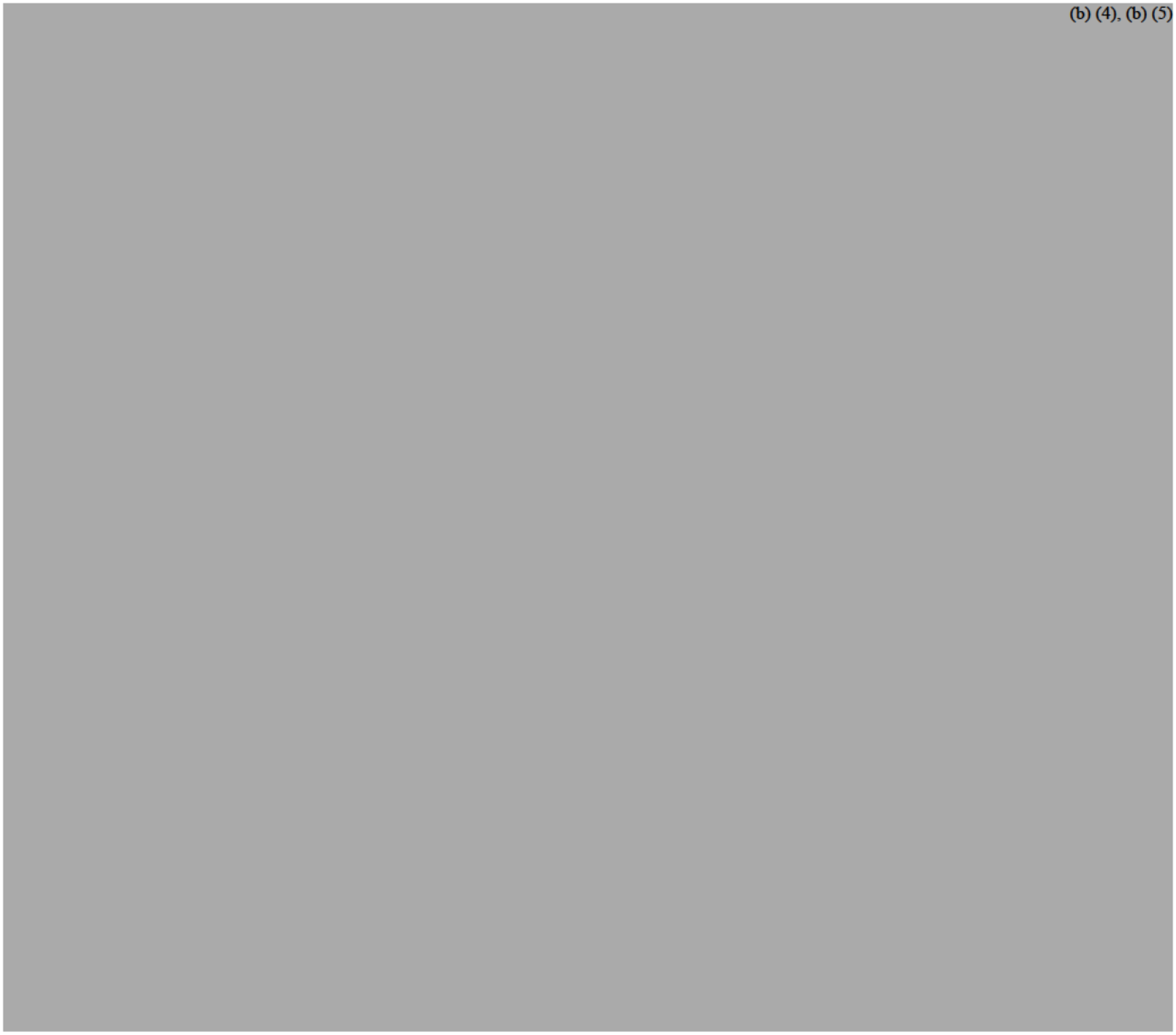
(b) (4), (b) (5)

Draft

Foundation for the National Institutes of Health (FNIH)
Accelerating Medicines Partnership (AMP)
Executive Committee (EC)
Teleconference Meeting Minutes
Friday, October 27, 2017
7:00 – 8:00 a.m. ET

Participants
Rosa Canet-Aviles (FNIH), Bob Carter (NIH/NIAMS), David Collier (Lilly), Francis Collins (NIH), Mikael Dolsten (Pfizer), Tanya Fischer (Sanofi), Ellen Gadbois (NIH), Richard Hodes (NIH/NIA), Marty Hodge (Pfizer), Steve Hoffmann (FNIH), Stephen Katz (NIH/NIAMS), Walter Koroshetz (NIH/NINDS), Joseph Menetski (FNIH), Dina Paltoo (NIH), Suzana Petanceska (NIH/NIA), Griffin Rodgers (NIH/NIDDK), Laurie Ryan (NIH/NIA), Jyoti Singh (NIH), Philip Smith (NIH/NIDDK), Paul Stoffels (J&J), Margaret Sutherland (NIH/NINDS), Larry Tabak (NIH), Melissa Thomas (Lilly), Lilit Vardanian (FNIH), David Wholley (FNIH)

(b) (4), (b) (5)



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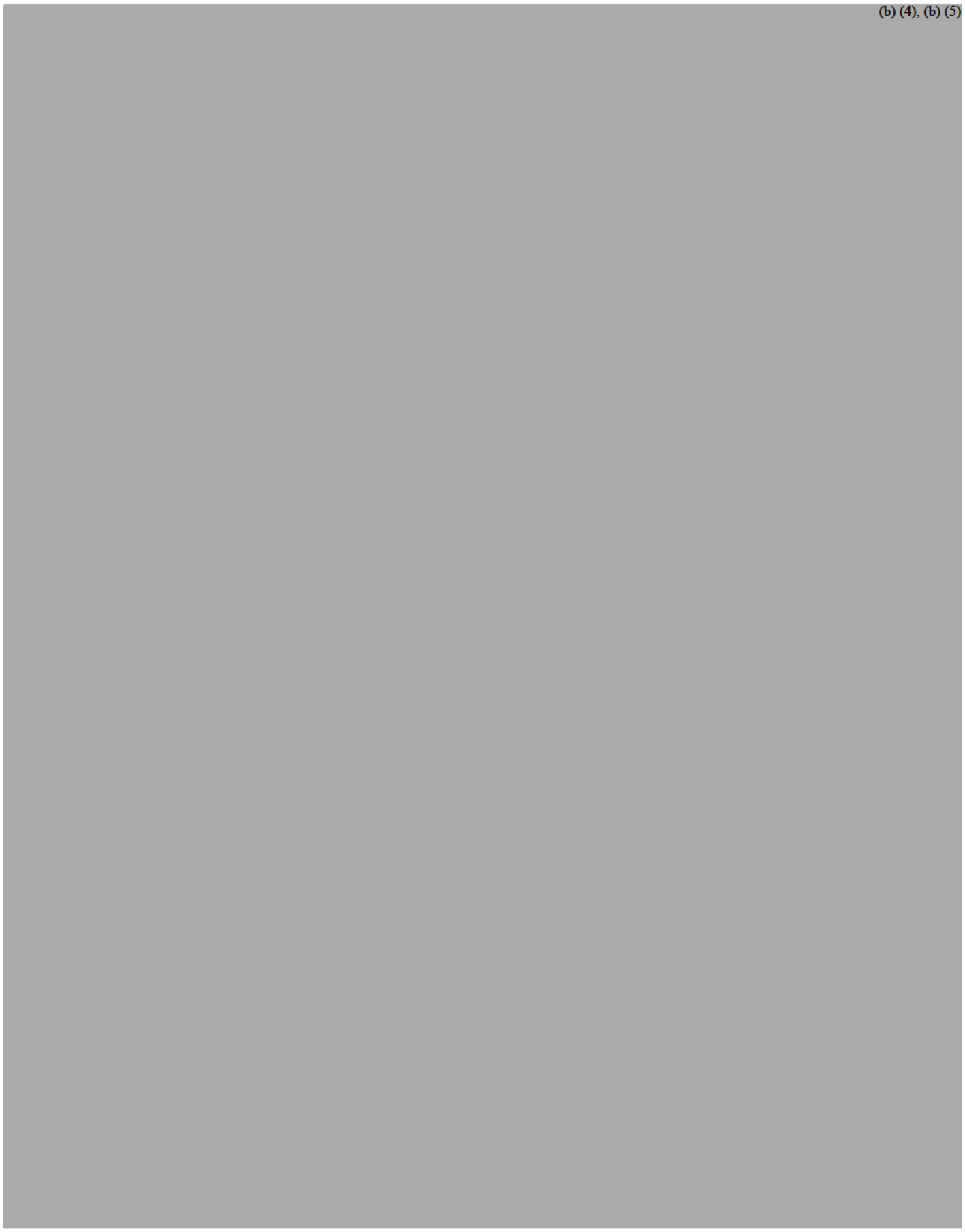
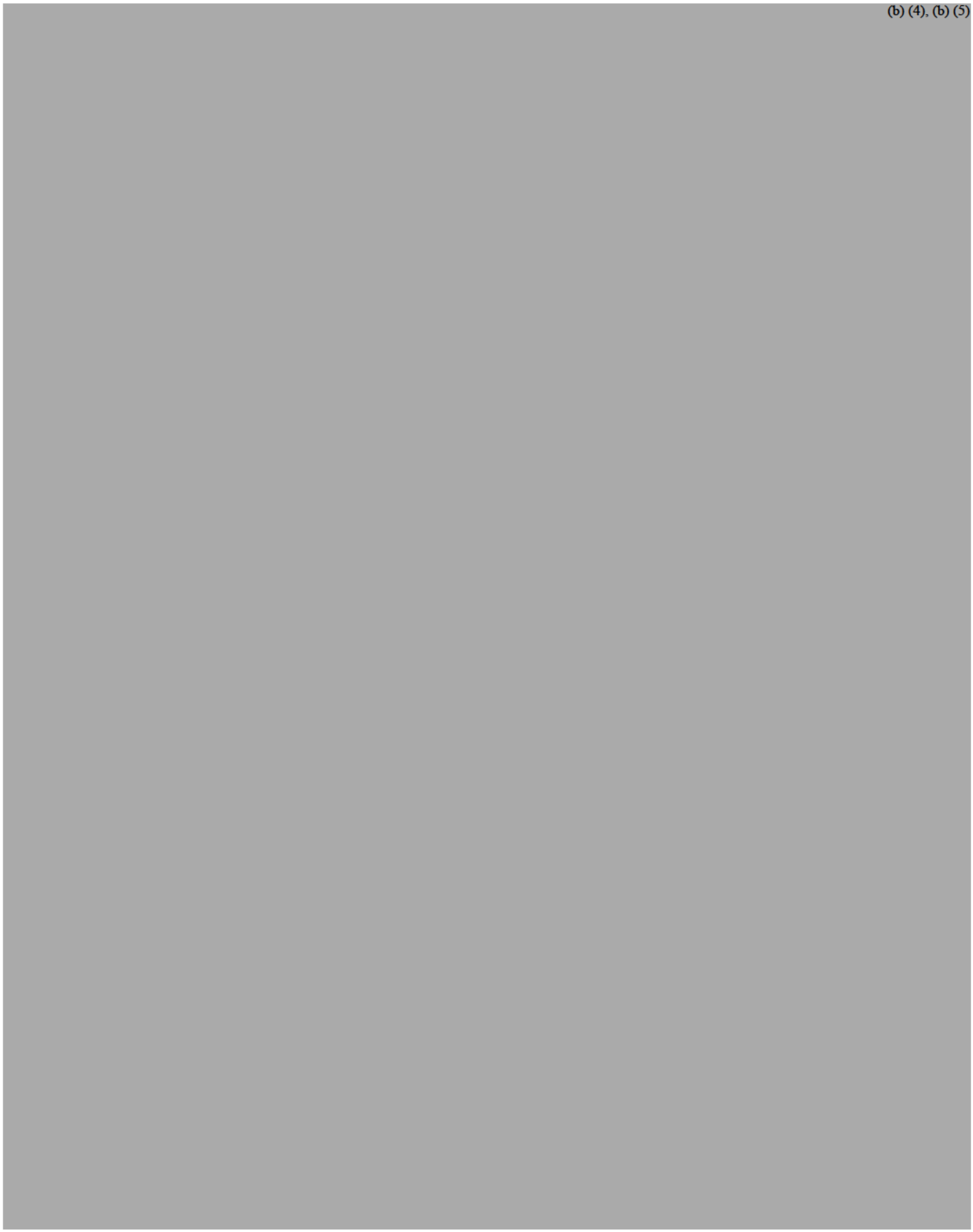


[redacted]


(b) (4), (b) (5)

Name	Attendance	Response
Melencio, Cheryl (FNIH) [T]	Meeting Organizer	None
Collins, Francis (NIH/OD) [E]	Required Attendee	Accepted
Dolsten, Mikael	Required Attendee	Accepted
Hodes, Richard (NIH/NIA) [E]	Required Attendee	Accepted
Katz, Stephen I. (NIH/NIAMS) [E]	Required Attendee	Accepted
Koroshetz, Walter (NIH/NINDS) [E]	Required Attendee	Accepted
Lifton, Richard	Required Attendee	Tentative
Lundberg, Jan	Required Attendee	Accepted
Rodgers, Griffin (NIH/NIDDK) [E]	Required Attendee	Accepted
Stoffels, Paul	Required Attendee	Accepted
Tabak, Lawrence (NIH/OD) [E]	Required Attendee	None
Terry, Sharon	Required Attendee	Accepted
Wholley, David (FNIH) [T]	Required Attendee	Accepted
Carter, Robert (NIH/NIAMS) [E]	Required Attendee	Accepted
Collier, David	Required Attendee	Accepted
Fischer, Tanya	Required Attendee	Accepted
Hodge, Martin	Required Attendee	Accepted
Ryan, Laurie (NIH/NIA) [E]	Required Attendee	None
Smith, Philip (NIH/NIDDK) [E]	Required Attendee	Accepted
Sutherland, Margaret (NIH/NINDS) [E]	Required Attendee	Accepted
Thomas, Melissa	Required Attendee	Accepted
Canet-Aviles, Rosa (FNIH) [T]	Required Attendee	Accepted
Gadbois, Ellen (NIH/OD) [E]	Required Attendee	Accepted
Grabus, Sheri	Required Attendee	None
Hoffmann, Steve (FNIH) [T]	Required Attendee	Accepted
Kamphaus, Tania (FNIH) [T]	Required Attendee	Accepted
Menetski, Joseph (FNIH) [T]	Required Attendee	Accepted
Paltoo, Dina (NIH/OD) [E]	Required Attendee	Accepted
Serrate-Sztein, Susana (NIH/NIAMS) [E]	Required Attendee	None
Singh, Jyoti (NIH/OD) [E]	Required Attendee	Accepted
Vardanian, Lilit (FNIH) [T]	Required Attendee	Tentative

From: Wholley, David (FNIH) [T]
Sent: Thu, 22 Feb 2018 18:31:46 +0000
To: Collins, Francis (NIH/OD) [E];Tabak, Lawrence (NIH/OD) [E]
Cc: Gadbois, Ellen (NIH/OD) [E];Singh, Jyoti (NIH/OD) [E]
Subject: Fw: AMP Executive Committee Teleconference -- NOTE FROM DR. DOLSTEN'S OFFICE

FYI-should not be an issue. Also David Collier (Lilly) will not be able to make the call so Suzana Petanceska (NIA) will take his place describing progress on AMP AD project B.
Sent from my BlackBerry 10 smartphone.

From: Melencio, Cheryl (FNIH) [T] <cmelencio@fnih.org>
Sent: Thursday, February 22, 2018 9:53 AM
To: Wholley, David (FNIH) [T]
Subject: FW: AMP Executive Committee Teleconference -- NOTE FROM DR. DOLSTEN'S OFFICE

FYI

Cheryl Melencio
Executive Assistant, Research Partnerships
Foundation for the National Institutes of Health
(301) 402-4970
fnih.org
11400 Rockville Pike Suite 600 North Bethesda, MD 20852

2017 Gold Stevie Award Winner for Organization of the Year

From: Protasiewicz, Ann [mailto:Ann.Protasiewicz@pfizer.com]
Sent: Thursday, February 22, 2018 9:49 AM
To: Melencio, Cheryl (FNIH) [T] <cmelencio@fnih.org>
Subject: RE: AMP Executive Committee Teleconference

Cheryl,

Mikael is schedule to depart at 11:45 a.m., so this will work out well as I need to print before he leaves.

Regarding the AMP call tomorrow, Mikael must attend a critical meeting beginning at 8 a.m. tomorrow. That given, he will need to get off of the AMP call 10-15 minutes early. Will you inform the appropriate participants of this?

Ann

Ann Martin Protasiewicz
Executive Assistant to
Mikael Dolsten, President
Worldwide Research and Development
Pfizer Inc.
235 East 42nd Street, Floor 22

New York, NY 10017
212-733-5859 (Office)
(b) (6) (Mobile)
E-Mail – ann.protasiewicz@pfizer.com

From: Melencio, Cheryl (FNIH) [T] [mailto:cmelencio@fnih.org]
Sent: Thursday, February 22, 2018 8:41 AM
To: Protasiewicz, Ann
Subject: [EXTERNAL] RE: AMP Executive Committee Teleconference

Hi Ann

The materials should be sent out this morning.

Cheryl

Cheryl Melencio
Executive Assistant, Research Partnerships
Foundation for the National Institutes of Health
(301) 402-4970
fnih.org
11400 Rockville Pike Suite 600 North Bethesda, MD 20852

2017 Gold Stevie Award Winner for Organization of the Year

From: Protasiewicz, Ann [mailto:Ann.Protasiewicz@pfizer.com]
Sent: Wednesday, February 21, 2018 6:03 PM
To: Melencio, Cheryl (FNIH) [T] <cmelencio@fnih.org>
Subject: RE: AMP Executive Committee Teleconference

Hi Cheryl,

When do you anticipate that the materials for the subject meeting will be distributed?

Ann

Ann Martin Protasiewicz
Executive Assistant to
Mikael Dolsten, President
Worldwide Research and Development
Pfizer Inc.
235 East 42nd Street, Floor 22
New York, NY 10017
212-733-5859 (Office)
(b) (6) (Mobile)
E-Mail – ann.protasiewicz@pfizer.com

-----Original Appointment-----
From: Melencio, Cheryl (FNIH) [T] [mailto:cmelencio@fnih.org]
Sent: Friday, December 1, 2017 11:14 AM

To: Melencio, Cheryl (FNIH) [T]; Collins, Francis (NIH/OD) [E]; Dolsten, Mikael; Hodes, Richard (NIH/NIA) [E]; Katz, Stephen I. (NIH/NIAMS) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Lifton, Richard; Lundberg, Jan; Rodgers, Griffin (NIH/NIDDK) [E]; Stoffels, Paul; Tabak, Lawrence (NIH/OD) [E]; Terry, Sharon MA; Wholley, David (FNIH) [T]; Carter, Robert (NIH/NIAMS) [E]; Collier, David; Fischer, Tanya; Hodge, Martin; Ryan, Laurie (NIH/NIA) [E]; Smith, Philip (NIH/NIDDK) [E]; Sutherland, Margaret (NIH/NINDS) [E]; Thomas, Melissa; Canet-Aviles, Rosa (FNIH) [T]; Gadbois, Ellen (NIH/OD) [E]; Sheri Grabus; Hoffmann, Steve (FNIH) [T]; Kamphaus, Tania (FNIH) [T]; tkerere@iqsolutions.com; Jennifer McCulley; Menetski, Joseph (FNIH) [T]; Paltoo, Dina (NIH/OD) [E]; Serrate-Sztein, Susana (NIH/NIAMS) [E]; Singh, Jyoti (NIH/OD) [E]; Vardanian, Lilit (FNIH) [T]; Boskent, Celeste (NIH/OD) [E]; Bronson, Charlette (NIH/NIA) [E]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Doswell, Greta (NIH/OD) [E]; Edmonds, Pamela; Yuliya Ilchyk; McManus, Ayanna (NIH/OD) [E]; Meltzer, Sherry (NIH/NIAMS) [E]; Morgan, Emily (FNIH) [T]; NIHDirectorMeetings; Poniente, Josefina; Poole, Charlene (NIH/NIDDK) [C]; Protasiewicz, Ann; Sheehan, Joan (NIH/NIA) [E]; Wood, Gretchen (NIH/OD) [E]; Zanellato, Ann; Craver, Stephanie (NIH/NIAMS) [E]; Donovan, Susan; Strisik, Nancy (nancy.strisik@sanofi.com)
Subject: [EXTERNAL] AMP Executive Committee Teleconference
When: Friday, February 23, 2018 7:00 AM-8:00 AM (UTC-05:00) Eastern Time (US & Canada).
Where: US/Canada: (b) (6) France: 0805 770 131 Germany: 0800 588 9700 UK: 08080 238 9879 Switzerland: 0800 661 155 Participant Code: (b) (6) Moderator Code: (b) (6) Project Code: (b) (6)

From: Wholley, David (FNIH) [T]
Sent: Wed, 7 Feb 2018 03:19:20 +0000
To: Collins, Francis (NIH/OD) [E];Tabak, Lawrence (NIH/OD) [E];Volkow, Nora (NIH/NIDA) [E];Koroshetz, Walter (NIH/NINDS) [E];Wolinetz, Carrie (NIH/OD) [E];Porter, Linda (NIH/NINDS) [E];Stein, Jack (NIH/NIDA) [E];Baker, Rebecca (NIH/OD) [E]
Cc: Biarnes, Michael (FNIH) [T];Menetski, Joseph (FNIH) [T]
Subject: Fw: BMAC today

FYI, first of two notes received from Rich Moscicki today.

Sent from my BlackBerry 10 smartphone.

From: Moscicki, Richard <rmoscicki@phrma.org>
Sent: Tuesday, February 6, 2018 6:31 PM
To: Wholley, David (FNIH) [T]
Subject: BMAC today

David, the BMAC reviewed the white paper today. The vote supported the science, scope, projects, and costs reflected in the base budget. General discomfort by most was voiced on the lack of any details now in the new governance section. It was felt strongly that industry representation was needed even if NIH retained final say. They will need to see a new governance section that reflects that. One member also objected to industry funding the Focused Medication Development program at NIDA, feeling that it was inappropriate for industry to fund NIH programs already in existance with other companies. There was a question as to why these smaller companies are not providing in kind contribution, (not cash, understood they are too small).

From: Wholley, David (FNIH) [T]
Sent: Thu, 8 Feb 2018 14:33:31 +0000
To: Collins, Francis (NIH/OD) [E];Tabak, Lawrence (NIH/OD) [E];Volkow, Nora (NIH/NIDA) [E];Koroshetz, Walter (NIH/NINDS) [E];Stein, Jack (NIH/NIDA) [E];Porter, Linda (NIH/NINDS) [E];Wolinetz, Carrie (NIH/OD) [E];Baker, Rebecca (NIH/OD) [E]
Cc: Biarnes, Michael (FNIH) [T];Menetski, Joseph (FNIH) [T]
Subject: FW: BMAC today

Fyi, my response to Rich's emails. Thank you Jack for your help in discussing this before I sent it.

From: Wholley, David (FNIH) [T]
Sent: Wednesday, February 7, 2018 6:34 PM
To: 'Moscicki, Richard' <rmoscicki@phrma.org>
Subject: RE: BMAC today

Rich,
Thanks for sharing results of what sounded like a pretty successful BMAC meeting. I appreciate the challenge this must have been and the results you were able to achieve. I have conveyed your thoughts on this to NIH as well as those in the other note you sent me and have been able to discuss at least some of this with them. My immediate answers would be as follows:

I understand the group's frustration about the lack of specifics in the governance sections of the new document. Previous governance language was either removed or changed considerably at NIH's request partly because of the uncertainty created by the larger issue Maria and I discussed with you on Friday night, and partly because NIH is simply not comfortable putting governance language in any document until it has gone through thorough OGC review. The two are linked, and I therefore don't see us being able to provide new language until the larger issues are settled. However I think there is abundant good faith on working out a fair governance structure that will be acceptable to all the partners once that occurs, and believe that the working group discussions we have had to date have been valuable in that regard.

As to your single member who was uncomfortable funding existing NIH programs in FMD, a basic premise of the entire partnership proposal since last summer has been that funding these programs is by far the most effective short-term way to deal with the crisis, as this is the only "shovel-ready" mechanism available over the next five years that can speed development and approval of OUD medications and formulations in a way that provides immediate impact. We have heard no other ideas as good as this. As for the role of the smaller companies involved in these programs, I think you can assure your member that they are indeed not only contributing drug in-kind but cash as well: NIDA's funds are only augmenting the R&D investments of the companies involved, who in many cases are risking everything they have on these development programs.

I have not had a chance to discuss the request for a review at 3 years to assess progress and direction, but don't think that will be a problem.

I understand the objection to the FMD budget reflecting identical years and need for ramp up, peak, ramp down due to attrition—it makes sense that the companies are looking at these as discrete

investments in particular programs that would not otherwise be executed. NIDA has agreed to take a further look at specific grant outlays and life cycles and provide requested breakdown and adjustment behind the $275M requested investment. I think this may take a bit of time however, and we probably cannot have this for you for a few days.

We are meanwhile working on getting you the revised version of the white paper suitable for your review with the FDABRC and distribution to the working group members either tonight or first thing tomorrow AM.

Thanks,
David

From: Moscicki, Richard [mailto:rmoscicki@phrma.org]
Sent: Tuesday, February 6, 2018 6:31 PM
To: Wholley, David (FNIH) [T] <dwholley@fnih.org>
Subject: BMAC today

David, the BMAC reviewed the white paper today. The vote supported the science, scope, projects, and costs reflected in the base budget. General discomfort by most was voiced on the lack of any details now in the new governance section. It was felt strongly that industry representation was needed even if NIH retained final say. They will need to see a new governance section that reflects that. One member also objected to industry funding the Focused Medication Development program at NIDA, feeling that it was inappropriate for industry to fund NIH programs already in existance with other companies. There was a question as to why these smaller companies are not providing in kind contribution, (not cash, understood they are too small).

From: Wholley, David (FNIH) [T]
Sent: Wed, 7 Feb 2018 03:22:50 +0000
To: Collins, Francis (NIH/OD) [E];Tabak, Lawrence (NIH/OD) [E];Volkow, Nora (NIH/NIDA) [E];Koroshetz, Walter (NIH/NINDS) [E];Porter, Linda (NIH/NINDS) [E];Stein, Jack (NIH/NIDA) [E];Wolinetz, Carrie (NIH/OD) [E];Baker, Rebecca (NIH/OD) [E]
Subject: Fw: BMAC

Second note from Rich M. Fyi
Sent from my BlackBerry 10 smartphone.

From: Moscicki, Richard <rmoscicki@phrma.org>
Sent: Tuesday, February 6, 2018 6:47 PM
To: Wholley, David (FNIH) [T]
Subject: BMAC

Actually, I forgot to mention another important add the BMAC would like, that would be a review at 3 years to assess progress and direction. BTW, they also didn't like the FMD budget reflecting identical years, also felt that there would ramp up, peak, ramp down due to attrition. Rich.

From: Wholley, David (FNIH) [T]
Sent: Mon, 26 Mar 2018 14:36:54 +0000
To: Collins, Francis (NIH/OD) [E];Sharpless, Norman (NIH/NCI) [E];Doroshow, James (NIH/NCI) [E]
Cc: Adam, Stacey (FNIH) [T];Peterson-Klaus, Jenny (FNIH) [T]
Subject: (b) (4) on the PACT EC

Dear Francis, Ned, and Jim:

(b) (4), (b) (5)

(b) (4), (b) (5) Thanks, David

David Wholley
Director, Research Partnerships
Foundation for the National Institutes of Health
(301) 594-6343
fnih.org
11400 Rockville Pike Suite 600 North Bethesda, MD 20852

2017 Gold Stevie Award Winner for Organization of the Year

From: Wholley, David (FNIH) [T]
Sent: Fri, 23 Mar 2018 20:50:26 +0000
To: Collins, Francis (NIH/OD) [E];Tabak, Lawrence (NIH/OD) [E];Wolinetz, Carrie (NIH/OD) [E];Volkow, Nora (NIH/NIDA) [E];Stein, Jack (NIH/NIDA) [E];Koroshetz, Walter (NIH/NINDS) [E];Porter, Linda (NIH/NINDS) [E];Baker, Rebecca (NIH/OD) [E];Freire, Maria (FNIH) [T];Hallett, Adrienne (NIH/OD) [E];Burklow, John (NIH/OD) [E];Myles, Renate (NIH/OD) [E]
Subject: Re: Call with Rich Moscicki

I think that is a good summary.

From: Collins, Francis (NIH/OD) [E]
Sent: Friday, March 23, 2018 4:29 PM
To: Tabak, Lawrence (NIH/OD) [E]; Wolinetz, Carrie (NIH/OD) [E]; Volkow, Nora (NIH/NIDA) [E]; Stein, Jack (NIH/NIDA) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Porter, Linda (NIH/NINDS) [E]; Baker, Rebecca (NIH/OD) [E]; Wholley, David (FNIH) [T]; Freire, Maria (FNIH) [T]; Hallett, Adrienne (NIH/OD) [E]; Burklow, John (NIH/OD) [E]; Myles, Renate (NIH/OD) [E]
Subject: Call with Rich Moscicki

Hi all,

Per agreement from last night's call, David and I spoke with Rich Moscicki at 11 AM today. I'm looping in Adrienne, John, and Renate to alert them to the next steps.

We first discussed the Omnibus – Rich was puzzled about the language that says that companies receiving money as part of the partnership have to match it. We explained that was a better alternative than others, and should be quite manageable.

Then we explained the status (still somewhat incomplete) of the ACD WG deliberations, and the formal outcome of the FNIH Board meeting.

Rich was moderately surprised, but his primary response was relief. He has apparently been getting a lot of push back from companies since he made the pitch to a subset of PhRMA CEOs and got a (somewhat grudging) affirmative response to the (b) (4), (b) (5) ask.

(b) (4), (b) (5)

David, please add any important things that I have inadvertently left out.

Francis

From: Wholley, David (FNIH) [T]
Sent: Wed, 21 Mar 2018 13:06:01 +0000
To: Collins, Francis (NIH/OD) [E]
Subject: RE: Opioids follow-up with PhRMA

Sure, just let me know what number to call in to and when. I'll keep checking email.

From: Collins, Francis (NIH/OD) [E]
Sent: Tuesday, March 20, 2018 9:30 PM
To: Wholley, David (FNIH) [T] <dwholley@fnih.org>
Subject: RE: Opioids follow-up with PhRMA

Trying to get all of the NIH and FNIH parties together tomorrow to discuss this…

From: Wholley, David (FNIH) [T]
Sent: Tuesday, March 20, 2018 12:52 PM
To: Collins, Francis (NIH/OD) [E] (b) (6)
Subject: Opioids follow-up with PhRMA

Francis,
We just heard from Ayanna that Thursday's opioid update meeting has been cancelled. I know we are all still to some extent digesting the outcome of the ACD Working Group and FNIH Board meetings, and that there is another shoe or two to drop—in particular what might be included in the omnibus spending bill Congress is considering, I guess. I am concerned however about communicating with PhRMA on some kind of timely basis about where things stand and would appreciate a few minutes of your time to get your perspective on that. Please let me know when it might be good to talk. Thanks,
David

David Wholley
Director, Research Partnerships
Foundation for the National Institutes of Health
(301) 594-6343
fnih.org
11400 Rockville Pike Suite 600 North Bethesda, MD 20852

2017 Gold Stevie Award Winner for Organization of the Year

From: Wholley, David (FNIH) [T]
Sent: Mon, 26 Mar 2018 17:21:23 +0000
To: Sharpless, Norman (NIH/NCI) [E];Collins, Francis (NIH/OD) [E];Doroshow, James (NIH/NCI) [E]
Cc: Adam, Stacey (FNIH) [T];Peterson-Klaus, Jenny (FNIH) [T]
Subject: RE: (b) (4) on the PACT EC

In answer to your question, (b) (4), (b) (5)
(b) (4), (b) (5)

From: Sharpless, Norman (NIH/NCI) [E]
Sent: Monday, March 26, 2018 12:14 PM
To: Wholley, David (FNIH) [T] <dwholley@fnih.org>; Collins, Francis (NIH/OD) [E] (b) (6); Doroshow, James (NIH/NCI) [E] (b) (6)
Cc: Adam, Stacey (FNIH) [T] <sadam@fnih.org>; Peterson-Klaus, Jenny (FNIH) [T] <jpeterson-klaus@fnih.org>
Subject: RE: (b) (4) on the PACT EC

(b) (4), (b) (5)

From: Wholley, David (FNIH) [T]
Sent: Monday, March 26, 2018 10:37 AM
To: Collins, Francis (NIH/OD) [E] (b) (6); Sharpless, Norman (NIH/NCI) [E] (b) (6); Doroshow, James (NIH/NCI) [E] (b) (6)
Cc: Adam, Stacey (FNIH) [T] <sadam@fnih.org>; Peterson-Klaus, Jenny (FNIH) [T] <jpeterson-klaus@fnih.org>
Subject: (b) (4) on the PACT EC

Dear Francis, Ned, and Jim:

(b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5) Thanks, David

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Director, Research Partnerships
Foundation for the National Institutes of Health
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fnih.org
11400 Rockville Pike Suite 600 North Bethesda, MD 20852

2017 Gold Stevie Award Winner for Organization of the Year

From: Wholley, David (FNIH) [T]
Sent: Wed, 14 Mar 2018 18:20:31 +0000
To: Collins, Francis (NIH/OD) [E];Sharpless, Norman (NIH/NCI) [E];Doroshow, James (NIH/NCI) [E];axel.x.hoos@gsk.com;thomas.hudson@abbvie.com;perez.edith@gene.com;Pazdur, Richard (FDA/OC);Marks, Peter (FDA/CBER);Roach, Nancy
Cc: Adam, Stacey (FNIH) [T];Peterson-Klaus, Jenny (FNIH) [T];Melencio, Cheryl (FNIH) [T]
Subject: Welcome to the PACT Executive Committee; Ballot for Joint Steering Committee Industry Co-Chair [Action Requested]
Attachments: JSC Co-Chair Ballot_ PrivatePartner_vF_update7.doc, PACT JSC Compiled Bios w CVs 03062018.pdf, PACT EC Roster and Description_vF.pdf, PACT JSC Roster and Description_vF.pdf

Dear PACT Executive Committee members,

Welcome to the PACT Executive Committee, and thank you for agreeing to be part of this exciting partnership! We are actively seeking a time slot for our first Committee teleconference. Stacey Adam and Jenny Peterson-Klaus will be supporting me here at FNIH in managing PACT and have already been in contact with your offices to get this first meeting and the remaining quarterly meetings on the calendar. The attached Word document outlines the membership, responsibilities, and meeting schedule for the Executive Committee as well as the role of the Extended Executive Committee.

Meanwhile we already have a bit of work for you. (b) (4)

(b) (4)

I am therefore asking that the six current voting members of the EC cast their vote using the attached ballot. The current voting members are:

Francis Collins
Jim Doroshow
Axel Hoos
Tom Hudson
Edith Perez
Ned Sharpless

Voting members: please note your top three choices and rank them by preference (1-2-3) on the attached ballot, and return the ballot to me no later than Tuesday, March 20 so we will have a decision in time for our next JSC call on March 23. Please copy Stacey Adam and Jenny Peterson-Klaus your vote.

If you have any questions or comments, please do not hesitate to contact us at any time.

Regards,
David Wholley

(b) (5)

(b) (5)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

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(b) (4)

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(b) (4)

(b) (4)

PACT Executive Committee (NCI/Industry/FDA/Patient Groups)	
Voting Members	**Non-Voting Members**
• **Francis Collins (NIH-OD)**	• **Richard Pazdur (OCE)**
• **Ned Sharpless (NCI-OD)**	• **Peter Marks (CBER)**
• **Jim Doroshow (NCI-DCTD)**	• **Nancy Roach (Fight CRC)**
• **Axel Hoos (GSK)**	
• **Edith Perez (Genentech)**	
• **Tom Hudson (AbbVie)**	

EC Membership

The membership of the EC (voting, except where otherwise noted) will include the following:

- The Director of the National Institutes of Health
- The Director of the National Cancer Institute
- The Director of the Division of Cancer Treatment and Diagnosis
- Two representatives from FDA (representing the OCE and CDER and CDRH, non-voting)
- A patient advocate representative
- Three senior-level executives from three different biopharmaceutical company partners (head of research and development or global head of oncology research or development)

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The PACT EC will be responsible for oversight of PACT, ensuring that the partnership overall is conducted efficiently and in the best interests of patients and the public health, and for communicating the value of PACT to its partners and the public. Specifically, the EC will be responsible for the following:

1. Providing general guidance for the overall strategy of PACT within the rapidly changing oncology landscape.
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The EC will be co-chaired by one senior official from NCI and one senior executive from one of the industry partners. The EC members and co-chairs will be decided by the participating partners. Meetings and operations of the EC will be staffed and supported by FNIH.

EC Process

Meeting Format and Frequency

The EC will meet quarterly by teleconference and will seek opportunities to meet periodically in person as schedules allow.

Voting

Voting will be by simple majority.

Communications of EC with Partners

To ensure effective communications with and input from all PACT stakeholders, an Extended Executive Committee, consisting of the EC members and of representatives from the private sector partners not currently included on the EC, will be established to receive regular updates on PACT and advise the EC on its progress and direction. The Extended EC will meet twice a year by teleconference. The EC and the Extended Executive Group will be convened and supported by FNIH.

PACT Joint Steering Committee
(NCI/FDA/Industry/Patient Advocate)

Voting Members

- **Jeff Abrams (NCI-CTEP)***
- **Helen Chen (NCI-CTEP)**
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- **David Patton (NCI-CBIIT)**
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- One to two non-voting representatives from selected patient advocate organizations
- Subject matter experts, such as academic investigators, whether funded by PACT or not; may be added at the JSC's discretion, but will be nonvoting
- At least one representative from FNIH (ex-officio, nonvoting)

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6. Overseeing active outreach to, and coordination with, other related cancer research and trial efforts and reviewing the immunotherapy landscape analysis curated by the Cancer Research Institute (CRI) and utilizing that information to guide the PACT effort in strategic decisions about trials and biomarkers.

From: Wholley, David (FNIH) [T]
Sent: Fri, 23 Mar 2018 01:13:43 +0000
To: Moscicki, Richard
Cc: Collins, Francis (NIH/OD) [E]
Subject: Can we speak tomorrow?

Rich, Francis and I would like to see if we can find some time tomorrow to talk with you about the opioid partnership. [redacted] (b) (6) late this evening, but is going to see if he can find some times that might work when he is back in the office tomorrow morning.

David

David Wholley
Director, Research Partnerships
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(301) 594-6343
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11400 Rockville Pike Suite 600 North Bethesda, MD 20852

2017 Gold Stevie Award Winner for Organization of the Year

From: Wholley, David (FNIH) [T]
Sent: Tue, 20 Mar 2018 17:15:31 +0000
To: Collins, Francis (NIH/OD) [E]
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Attachments: JSC Co-Chair Ballot_ PrivatePartner_vF_update7.doc, PACT JSC Compiled Bios w CVs 03062018.pdf, PACT EC Roster and Description_vF.pdf, PACT JSC Roster and Description_vF.pdf

Dear Francis :

Can we please get your vote as requested? We would like to have something in place by this Friday's PACT JSC call if at all possible.

Thanks, David Wholley

From: Wholley, David (FNIH) [T]
Sent: Wednesday, March 14, 2018 2:20 PM
To: Collins, Francis (NIH/OD) [E] (b) (6); Sharpless, Norman (NIH/NCI) [E] (b) (6); Doroshow, James (NIH/NCI) [E] (b) (6) 'axel.x.hoos@gsk.com' <axel.x.hoos@gsk.com>; 'thomas.hudson@abbvie.com' <thomas.hudson@abbvie.com>; 'perez.edith@gene.com' <perez.edith@gene.com>; Pazdur, Richard (FDA/OC) (b) (6); Marks, Peter (FDA/CBER) (b) (6); Roach, Nancy <nancy.roach@fightcolorectalcancer.org>
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(b) (5)

(b) (5)

(b) (4)

(b) (4)

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From: Wholley, David (FNIH) [T]
Sent: Tue, 20 Mar 2018 19:45:22 +0000
To: Collins, Francis (NIH/OD) [E]
Subject: FW: Opioid PPP

Hi Francis. He left me a voicemail as well. I am not in the office but available by phone whenever. Am guessing it has already been a long day for you.

From: Moscicki, Richard [mailto:rmoscicki@phrma.org]
Sent: Tuesday, March 20, 2018 2:49 PM
To: Wholley, David (FNIH) [T] <dwholley@fnih.org>
Subject: Opioid PPP

Hi David, I need to touch base with you on where the PPP stands. I am getting inquiries from our members as its been radiosilence and need to give them an update. We are also hearing rumors regarding the PPP in the omnibus and I need to know what NIH knows about this. In my communication with the members I will also try to get a handle on what each company is thinking in its in kind contribution, unless you already have that data. I am free this afternoon, (b) (6). Rich.

From: Wholley, David (FNIH) [T]
Sent: Mon, 5 Mar 2018 22:49:47 +0000
To: Collins, Francis (NIH/OD) [E]
Cc: Gadbois, Ellen (NIH/OD) [E];Singh, Jyoti (NIH/OD) [E]
Subject: FW: Touch base on AMP

Francis – FYI, Paul Stoffels was not able to make my call this morning following up on the AMP EC, but I did speak with his VP External Affairs and below is the upshot. David

---

From: Wholley, David (FNIH) [T]
Sent: Monday, March 5, 2018 5:47 PM
To: 'Castillejos, Carlos [JJCUS]' <CCastil6@its.jnj.com>
Cc: Stoffels, Paul [JJCUS] <PStoffe4@its.jnj.com>; Melencio, Cheryl (FNIH) [T] <cmelencio@fnih.org>; Zanellato, Ann [JJCUS] <AZanell2@its.jnj.com>; Steel, Joanna [JJCUS] <jsteel1@ITS.JNJ.com>
Subject: RE: Touch base on AMP

Dear Carlos:
Since we were not able to have everyone on our call today I wanted confirm with you the following:

- Francis Collins has 45 minutes on the HEVER agenda Saturday morning, April 14 beginning at 9AM. He plans to give brief updates on four partnerships, including some time for Q&A: 1) The Cancer Moonshot (including the Partnership for Accelerating Cancer Therapies [PACT]), 2) AMP , 3) the partnership on opioids (addiction and pain) currently in development, 4) the Coalition for African Research and Innovation (currently involving the Gates Foundation, the World Economic Forum and NIH, but not FNIH).
- My team will draft slides for Francis to review prior to the meeting for the first three of these initiatives. As Paul knows, there are several AMP Steering Committee meetings over the next 2-3 weeks that will provide input to the progress report on AMP in particular.
- I understand that immediately following Francis's presentation on the 14th, Pierre Meulien is scheduled to lead a 90-minute update and discussion on the progress of IMI. Paul had offered to broker further discussions with IMI about how their proposed research agendas compare with potential plans for AMP. I will leave to Paul how he would like to handle that discussion and whether it should occur before or after HEVER as a result.

Please let me know how I may be of further help.
Thanks,
David

From: Castillejos, Carlos [JJCUS] [mailto:CCastil6@its.jnj.com]
Sent: Friday, February 23, 2018 5:57 PM
To: Wholley, David (FNIH) [T] <dwholley@fnih.org>
Cc: Stoffels, Paul [JJCUS] <PStoffe4@its.jnj.com>; Melencio, Cheryl (FNIH) [T] <cmelencio@fnih.org>; Zanellato, Ann [JJCUS] <AZanell2@its.jnj.com>; Steel, Joanna [JJCUS] <jsteel1@ITS.JNJ.com>
Subject: Re: Touch base on AMP

Thanks for your swift response David.

Cheryl, could you kindly work with Ann who manages Paul's agenda and Joanna.

Kind regards

Carlos

Pardon any brevity, sent from mobile

On Feb 23, 2018, at 5:27 PM, Wholley, David (FNIH) [T] <dwholley@fnih.org> wrote:

Thanks, Carlos. Cheryl Melencio, who keeps my calendar, will work with you on a suitable time.
David

From: Castillejos, Carlos [JJCUS] [mailto:CCastil6@its.jnj.com]
Sent: Friday, February 23, 2018 4:10 PM
To: Wholley, David (FNIH) [T] <dwholley@fnih.org>
Cc: Stoffels, Paul [JJCUS] <PStoffe4@its.jnj.com>
Subject: Touch base on AMP

Dear David

Hope you're doing well.

After reviewing the deck of the AMP Executive Committee with Paul, we would appreciate some minutes of your time to connect on the outstanding issues mentioned on slide 3. Particularly to discuss the Hever update and the potential connection between AMP portfolio and IMI/EFPIA projects.

Agendas in the upcoming weeks are pretty packed but since the Hever meeting is just a couple of months ahead, we would truly appreciate if you could make yourself available for a brief call. Below I'm listing a few available slots on Paul's calendar, hopefully one of them will work for you but if not, could you kindly propose a few alternatives.

Monday March 5th at 2:30 p.m

Friday March 9th at 9:00 a.m.

Tuesday March 13th at 5:30 p.m.

Wednesday March 12th at 5:30 p.m

Looking forward to talking to you soon

Carlos

Carlos F Castillejos, MD, Sc.D.
VP, External Affairs – Science & Medicine
Office of the Chief Scientific Officer
<image001.png>
Phone: 908. 927-7548 | Mobile: (b) (6) | ccastil6@its.jnj.com
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From: Wholley, David (FNIH) [T]
Sent: Tue, 20 Mar 2018 16:52:25 +0000
To: Collins, Francis (NIH/OD) [E]
Subject: Opioids follow-up with PhRMA

Francis,
We just heard from Ayanna that Thursday's opioid update meeting has been cancelled. (b) (4)

(b) (4)

(b) (4) Please let me know when it might be good to talk. Thanks,

David

David Wholley
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2017 Gold Stevie Award Winner for Organization of the Year

From: Wholley, David (FNIH) [T]
Sent: Wed, 18 Apr 2018 22:41:46 +0000
To: Melencio, Cheryl (FNIH) [T];Canet-Aviles, Rosa (FNIH) [T];Hoffmann, Steve (FNIH) [T];Kamphaus, Tania (FNIH) [T];Collins, Francis (NIH/OD) [E];Tabak, Lawrence (NIH/OD) [E];Gadbois, Ellen (NIH/OD) [E];Singh, Jyoti (NIH/OD) [E];Wood, Gretchen (NIH/OD) [E];Burrus-Shaw, Cyndi (NIH/OD) [E];NIHDirectorMeetings;McManus, Ayanna (NIH/OD) [E];Menetski, Joseph (FNIH) [T];Morgan, Emily (FNIH) [T];Di Mantova, Emma (NIH/OD) [E]
Subject: RE: AMP Pre-Call
Attachments: AMP EC Slides April 25 - DRAFT.pptx, 2018-02-23_AMP EC Teleconference minutes final draft.docx, Copy of AMP EC Attendance April 27 2018.xlsx

Attached please find the materials for tomorrow afternoon's AMP EC Pre-Call: draft slide set for the April 25 EC call, draft minutes from our last AMP EC meeting in February, and the latest attendee response listing. I look forward to the discussion. David

Accelerating Medicines PartnershipExecutive Committee Update

25 April, 2018

FNIH
Foundation for the National Institutes of Health

(b) (4), (b) (5)

(b) (4), (b) (5)

Accelerating Medicines PartnershipType 2 Diabetes

FNIH

Foundation for the
National Institutes of Health

NIH - 004632

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Accelerating Medicines PartnershipParkinson's Disease

FNIH

Foundation for the
National Institutes of Health

NIH - 004644

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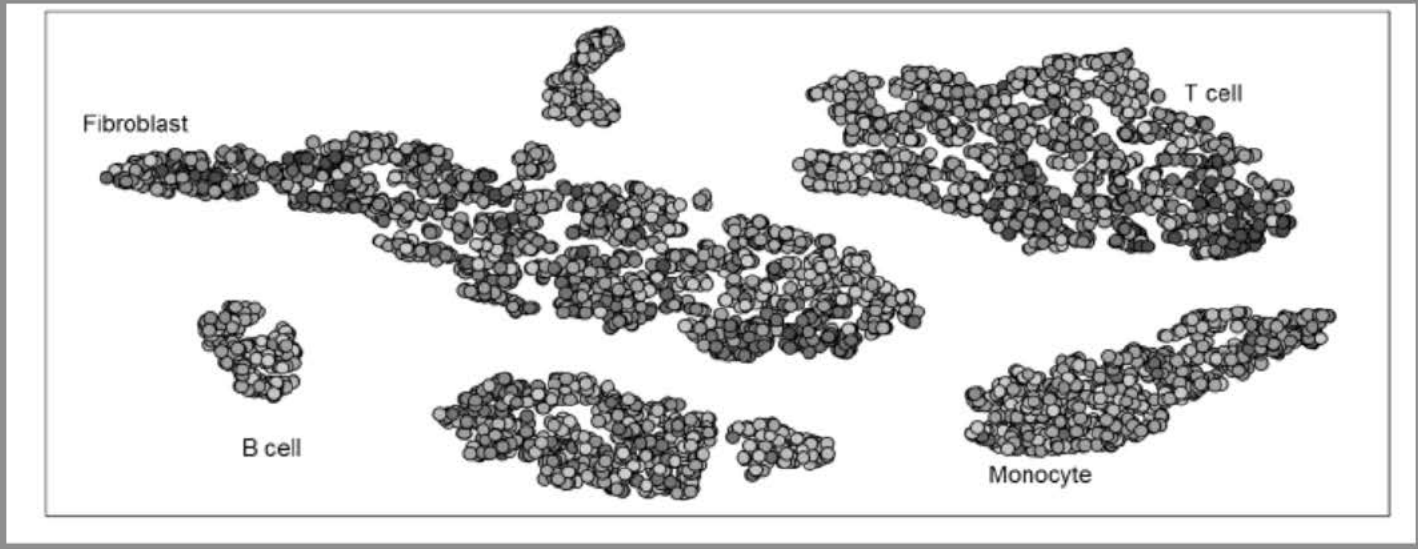
(b) (4), (b) (5)

Accelerating Medicines PartnershipRA/SLE



FNIH

Foundation for the
National Institutes of Health

NIH - 004653

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Accelerating Medicines PartnershipAlzheimer's Disease

FNIH

Foundation for the National Institutes of Health

NIH - 004661

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(b) (4), (b) (5)

(b) (4), (b) (5)

Upcoming EC meetings

- **Next MeetingAMP EEC: Friday, June 29 from 7:00 am – 8:30 am**

Backup Slides

NIH - 004669

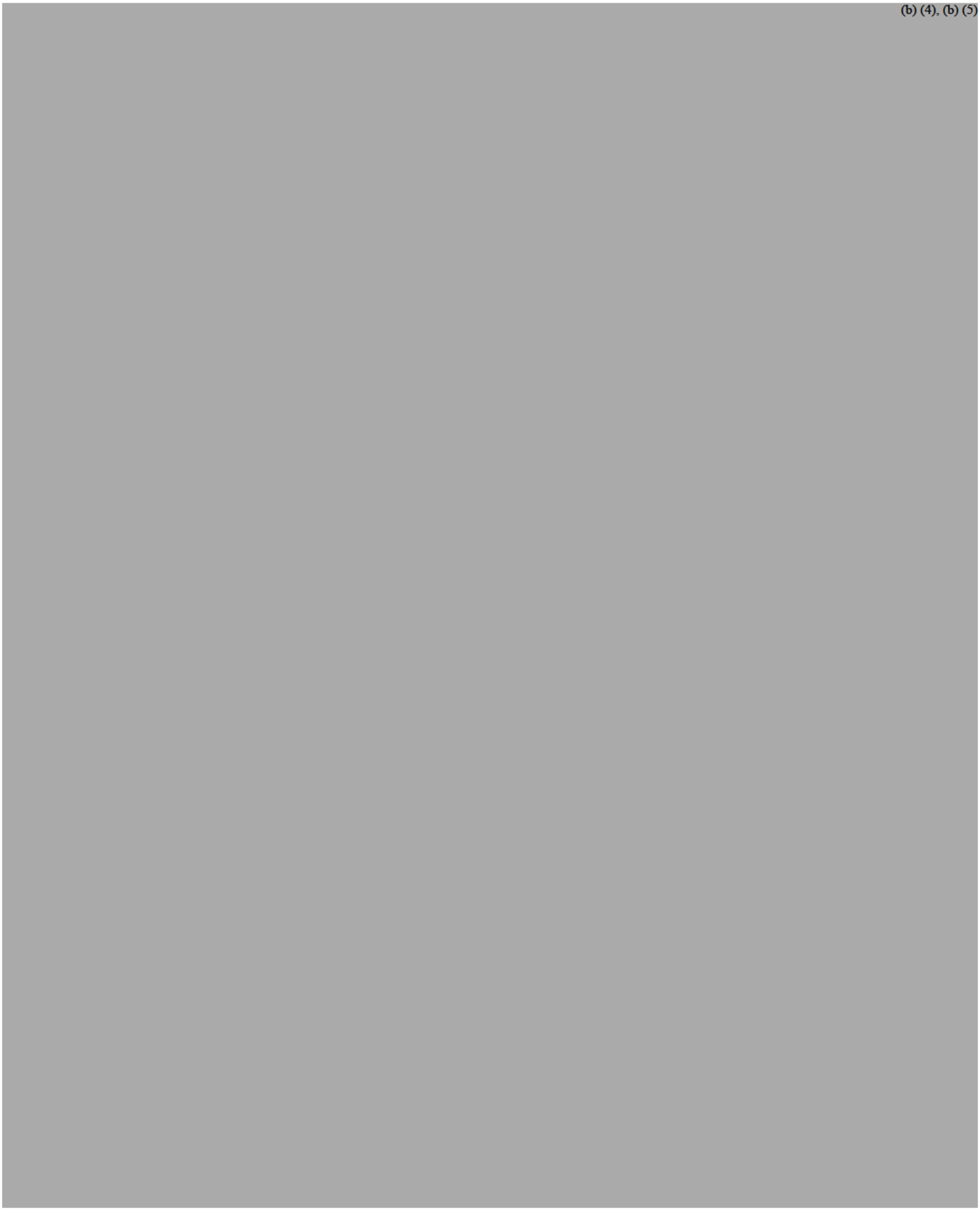
(b) (4), (b) (5)

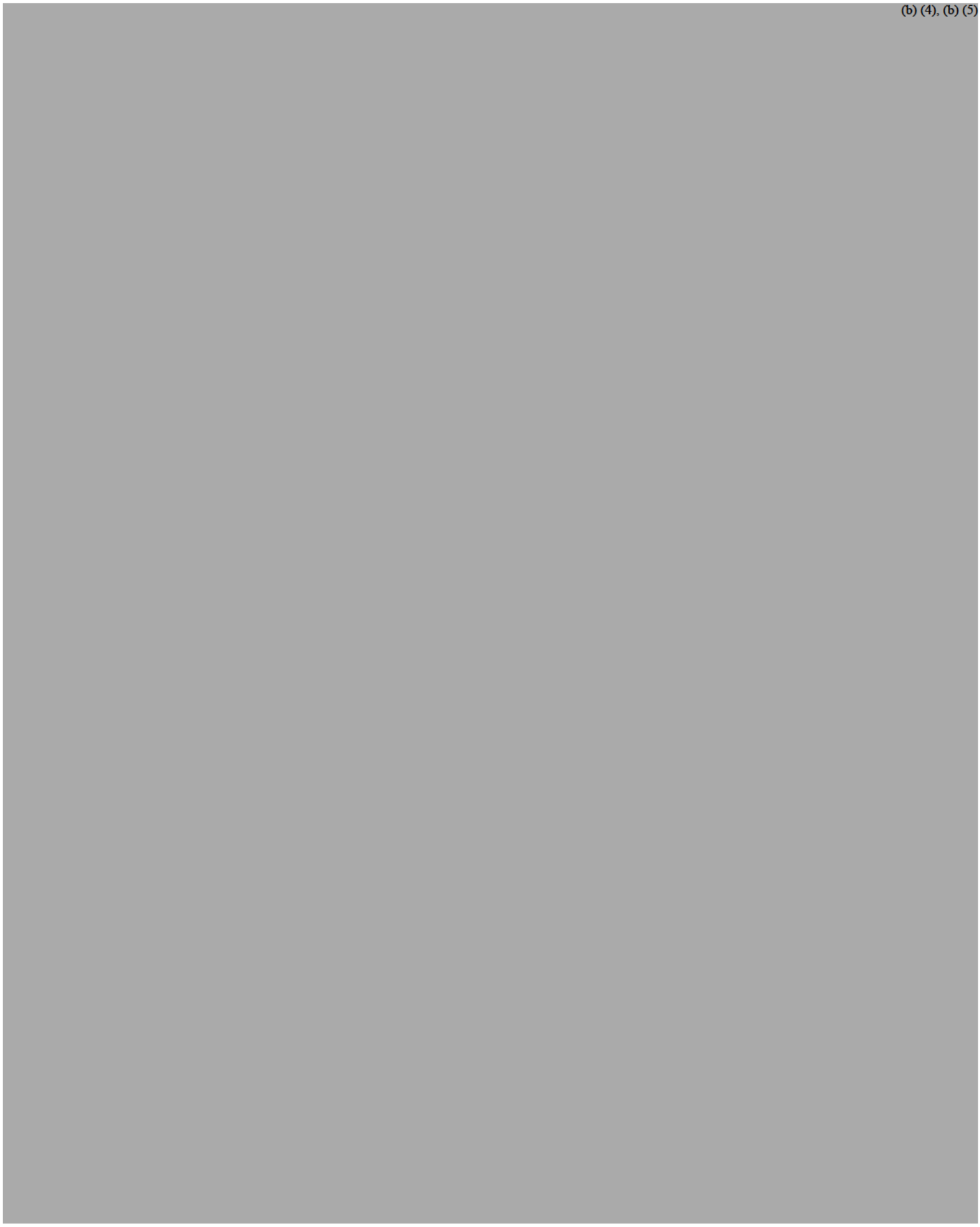
Foundation for the National Institutes of Health (FNIH)
Accelerating Medicines Partnership (AMP)
Executive Committee (EC)
Teleconference Meeting Minutes

Friday, February 23, 2018
7:00 – 8:00 a.m. ET

Participants
Rosa Canet-Avilés (FNIH), Bob Carter (NIH/NIAMS), Francis Collins (NIH), Mikael Dolsten (Pfizer), Tanya Fischer (Sanofi), Ellen Gadbois (NIH), Richard Hodes (NIH/NIA), Steve Hoffmann (FNIH), Tania Kamphaus (FNIH), Walter Koroshetz (NIH/NINDS), Jan Lundberg (Lilly), Suzana Petanceska (NIH/NIA), Griffin Rodgers (NIH/NIDDK), Laurie Ryan (NIH/NIA), Susana Serrate-Sztein (NIH/NIAMS), Jyoti Singh (NIH), Phil Smith (NIH/NIDDK), Paul Stoffels (J&J), Marg Sutherland (NIH/NINDS), Larry Tabak (NIH), Melissa Thomas (Lilly), David Wholley (FNIH)

(b) (4), (b) (5)





(b) (4), (b) (5)

Name	Attendance	Response
Berlyne, Debby (science writer)	Required Attendee	Accepted
Canet-Aviles, Rosa (FNIH) [T]	Required Attendee	Accepted
Carter, Robert (NIH/NIAMS) [E]	Required Attendee	Accepted
Collier, David	Required Attendee	Accepted
Collins, Francis (NIH/OD) [E]	Required Attendee	Accepted
Dolsten, Mikael	Required Attendee	Accepted
Fischer, Tanya	Required Attendee	Accepted
Gadbois, Ellen (NIH/OD) [E]	Required Attendee	Accepted
Hodes, Richard (NIH/NIA) [E]	Required Attendee	Accepted
Hodge, Martin	Required Attendee	Accepted
Hoffmann, Steve (FNIH) [T]	Required Attendee	Accepted
Kamphaus, Tania (FNIH) [T]	Required Attendee	Accepted
Katz, Stephen I. (NIH/NIAMS) [E]	Required Attendee	Accepted
Koroshetz, Walter (NIH/NINDS) [E]	Required Attendee	Tentative
Lifton, Richard	Required Attendee	Accepted
Lundberg, Jan	Required Attendee	Declined
Melencio, Cheryl (FNIH) [T]	Meeting Organizer	None
Menetski, Joseph (FNIH) [T]	Required Attendee	Accepted
Paltoo, Dina (NIH/OD) [E]	Required Attendee	Accepted
Petanceska, Suzana (NIH/NIA) [E]	Required Attendee	None
Rodgers, Griffin (NIH/NIDDK) [E]	Required Attendee	Accepted
Ryan, Laurie (NIH/NIA) [E]	Required Attendee	None
Serrate-Sztein, Susana (NIH/NIAMS) [E]	Required Attendee	None
Singh, Jyoti (NIH/OD) [E]	Required Attendee	Accepted
Smith, Philip (NIH/NIDDK) [E]	Required Attendee	Accepted
Stoffels, Paul	Required Attendee	Accepted
Sutherland, Margaret (NIH/NINDS) [E]	Required Attendee	Accepted
Tabak, Lawrence (NIH/OD) [E]	Required Attendee	None
Terry, Sharon	Required Attendee	Tentative
Thomas, Melissa	Required Attendee	Accepted
Wholley, David (FNIH) [T]	Required Attendee	Accepted

From: Wholley, David (FNIH) [T]
Sent: Wed, 18 Apr 2018 15:20:00 +0000
To: Collins, Francis (NIH/OD) [E]
Subject: RE: Brief report on Hever meeting

Francis:
Just curious whether there was any specific feedback on 1) AMP T2D portal getting access to the IMI SUMMIT study data and 2) discussion of whether the T2D knowledge portal should be extended to other disorders – and whether there are any concrete action items for me to follow those up. We have our AMP EC pre-call tomorrow (slides will be out shortly), so fine if you want to wait till then to discuss.

From: Collins, Francis (NIH/OD) [E]
Sent: Monday, April 16, 2018 6:01 PM
To: Tabak, Lawrence (NIH/OD) [E] (b) (6); Wolinetz, Carrie (NIH/OD) [E] (b) (6); Burklow, John (NIH/OD) [E] (b) (6); Hallett, Adrienne (NIH/OD) [E] (b) (6); Wholley, David (FNIH) [T] <dwholley@fnih.org>; Eiss, Robert (NIH/FIC) [E] (b) (6); Glass, Roger (NIH/FIC) [E] (b) (6); Dishman, Eric (NIH/OD) [E] (b) (6); Devaney, Stephanie (NIH/OD) [E] (b) (6); Volkow, Nora (NIH/NIDA) [E] (b) (6); Koroshetz, Walter (NIH/NINDS) [E] (b) (6); Sharpless, Norman (NIH/NCI) [E] (b) (6); Doroshow, James (NIH/NCI) [E] (b) (6)
Cc: Austin, Christopher (NIH/NCATS) [E] (b) (6)
Subject: Brief report on Hever meeting

Hi all,

I attended part of the 23rd annual Hever meeting in NYC this weekend, where the heads of R&D of the largest biopharmaceutical companies gathered to discuss common interests. I've been invited to this meeting for the last seven years, and it has provided a good venue for initiating collaborations and partnerships. AMP got started here. PACT got a big boost, and the opioids partnership was a major topic of discussion last year.

I was only able to be present for Saturday morning, but Chris Austin represented NIH for the rest of the meeting (I'll leave it to him to share notes on those items if appropriate). I was asked to summarize no less than five topics in 75 minutes, including discussion. I used the attached ppt file. As each of you have important roles in one or more of these projects, I'm sending this around as a quick summary of the discussion. Because of Chatham House rules I am not naming names.

- AMP – Hever members are generally quite happy with how this project, launched in Feb. 2014, has gone. The possibility of AMP 2.0 was well received, but no definite commitments. The main questions were about the new project on Parkinson's disease – Q: will this help identify subsets? A: yes. Q: Will the study include use of wearable sensors? A: Likely yes. David Nicholson (Allergan) spoke to me at the break, wanted to know more about the PD project, will be reaching out to me or Walter K.
- PACT – Most of the 12 companies that are partnering on PACT were there and seem happy with the way the project is taking shape. Questions were raised about how PACT could involve

diagnostic companies. There was also an exhortation from one leader about pushing for early data release, even before the 6 months traditional embargo.

- Opioids – The NIH Director's statement about not accepting cash from industry had been issued the day before, and many Hever members had already seen it. There was some general hand-wringing from companies that have played no role in the current crisis about why they should be tarred with the same brush as those facing litigation. I expressed sympathy but explained why we had to follow the recommendations from ACD and FNIH. I was urged to meet as soon as possible with the CEOs on the BMAC, in order to keep that relationship solid. After some kvetching, the Hever members moved on to agree that a partnership would still be appropriate and valuable. They noted that this new arrangement would free up NIH to use its usual competitive mechanisms when appropriate. I urged them to complete the survey of assets. There was a very brief discussion of how to attach financial value to assets. Since we at NIH are no longer interested in having these add up to a certain dollar contribution (as compared to IMI, where this is a very big deal), I thought they might not be so concerned – but apparently they will still want to do this (tax reasons?), and the comment was made that "asset valuation needs to survive internal audit".
- Coalition for African Research and Innovation (CARI) – Paul Stoffels (now serving as Hever chair) had commissioned a Dalberg survey on clinical trial capacity in Africa, and that had been discussed the day before on a conference call with several of the companies. So that drove the discussion. It's clear that Dalberg had rather incomplete data, especially on Francophone countries. Paul agreed to carry the ball on next steps for industry's role with CARI; there was general enthusiasm for the idea of creating a network of the "tier 1" institutions, to try to develop better standards and overall capacity. The regulatory challenges of working in Africa were also mentioned repeatedly.
- All of Us – The Hever members have not been tracking this closely, and were interested and intrigued to see how far the beta test has come. The discussion focused on how this could be a really useful platform for rapid enrollment and the ability to carry out real world trials.

That's kind of it from me. Chris, please add anything I've missed.

Francis

From: Wholley, David (FNIH) [T]
Sent: Thu, 5 Apr 2018 17:36:06 +0000
To: Collins, Francis (NIH/OD) [E];Tabak, Lawrence (NIH/OD) [E];Volkow, Nora (NIH/NIDA) [E];Koroshetz, Walter (NIH/NINDS) [E];Stein, Jack (NIH/NIDA) [E];Porter, Linda (NIH/NINDS) [E];Wolinetz, Carrie (NIH/OD) [E];Baker, Rebecca (NIH/OD) [E];Shapiro, Neil (NIH/OD) [E]
Cc: Menetski, Joseph (FNIH) [T];Biarnes, Michael (FNIH) [T]
Subject: RE: budget from opioids white paper

(b) (5)

From: Wholley, David (FNIH) [T]
Sent: Thursday, April 5, 2018 1:27 PM
To: Collins, Francis (NIH/OD) [E] (b) (6); Tabak, Lawrence (NIH/OD) [E] (b) (6); Volkow, Nora (NIH/NIDA) [E] (b) (6); Koroshetz, Walter (NIH/NINDS) [E] (b) (6); Stein, Jack (NIH/NIDA) [E] (b) (6) Porter, Linda (NIH/NINDS) [E] (b) (6); Wolinetz, Carrie (NIH/OD) [E] (b) (6); Baker, Rebecca (NIH/OD) [E] (b) (6) Shapiro, Neil (NIH/OD) [E] (b) (6)
Cc: Menetski, Joseph (FNIH) [T] <jmenetski@fnih.org>; Biarnes, Michael (FNIH) [T] <mbiarnes@fnih.org>
Subject: budget from opioids white paper

As requested

David Wholley
Director, Research Partnerships
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fnih.org
11400 Rockville Pike Suite 600 North Bethesda, MD 20852

2017 Gold Stevie Award Winner for Organization of the Year

From: Wholley, David (FNIH) [T]
Sent: Sun, 8 Apr 2018 23:12:25 +0000
To: Collins, Francis (NIH/OD) [E]
Subject: Re: Discussion of IMI SUMMIT data at the Hever meeting

I agree completely. Thanks for taking this up.
Sent from my BlackBerry 10 smartphone.

From: Collins, Francis (NIH/OD) [E]
Sent: Saturday, April 7, 2018 5:17 PM
To: Wholley, David (FNIH) [T]
Subject: RE: Discussion of IMI SUMMIT data at the Hever meeting

Hi David,

I'll see what I can do. [redacted] (b) (5)

FC

From: Wholley, David (FNIH) [T]
Sent: Friday, April 06, 2018 12:54 PM
To: Collins, Francis (NIH/OD) [E] [redacted] (b) (6)
Subject: Discussion of IMI SUMMIT data at the Hever meeting

Francis:
You may remember that at the FNIH Board meeting a few weeks back I briefly mentioned to you several issues related to enhancing the AMP T2D portal on which I could use your help. [redacted] (b) (5)

[redacted] (b) (5)

Thanks for agreeing to discuss this. Please let me know if you need any additional information.
Thanks, David

David Wholley
Director, Research Partnerships
Foundation for the National Institutes of Health
(301) 594-6343
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11400 Rockville Pike Suite 600 North Bethesda, MD 20852

2017 Gold Stevie Award Winner for Organization of the Year

From: Wholley, David (FNIH) [T]
Sent: Fri, 13 Apr 2018 02:19:22 +0000
To: Collins, Francis (NIH/OD) [E];Pelis, Kim (NIH/OD) [E];George, Jill (NIH/OD) [E];Eiss, Robert (NIH/FIC) [E];Austin, Christopher (NIH/NCATS) [E]
Subject: RE: Hever agenda

Francis, here are some suggested questions for you to choose from.

AMP:

(b) (5)

PACT:

(b) (5)

Opioids Partnership:

(b) (5)

David

From: Collins, Francis (NIH/OD) [E]
Sent: Wednesday, April 11, 2018 3:48 PM
To: Wholley, David (FNIH) [T] <dwholley@fnih.org>; Pelis, Kim (NIH/OD) [E] (b) (6);

George, Jill (NIH/OD) [E] (b) (6) Eiss, Robert (NIH/FIC) [E] (b) (6);
Austin, Christopher (NIH/NCATS) [E] (b) (6)
Subject: RE: Hever agenda

Thanks, David. To start the discussions, I will need to pose questions to Hever about each of the topics.

Care to suggest questions for AMP, PACT, and opioids/pain PPP?

FC

From: Wholley, David (FNIH) [T]
Sent: Wednesday, April 11, 2018 10:24 AM
To: Collins, Francis (NIH/OD) [E] (b) (6) Pelis, Kim (NIH/OD) [E] (b) (6)
George, Jill (NIH/OD) [E] (b) (6); Eiss, Robert (NIH/FIC) [E] (b) (6)
Subject: RE: Hever agenda

Francis,

Great news. Have we given you everything you need for this from our end? BTW, I will have blackberry on Friday evening and Saturday morning in case you have questions, and if you need to call my cell is (b) (6). Hope it goes well!

From: Collins, Francis (NIH/OD) [E]
Sent: Wednesday, April 11, 2018 5:59 AM
To: Pelis, Kim (NIH/OD) [E] (b) (6); George, Jill (NIH/OD) [E] (b) (6); Eiss, Robert (NIH/FIC) [E] (b) (6); Wholley, David (FNIH) [T] <dwholley@fnih.org>
Subject: FW: Hever agenda

From: Jill Payne [mailto:jill@ptbusinessgroups.com]
Sent: Wednesday, April 11, 2018 5:50 AM
To: Collins, Francis (NIH/OD) [E] (b) (6)>; 'MD Paul Stoffels' <pstoffe4@its.jnj.com>
Cc: 'Prof Trevor M Jones CBE FMedSci' <trevor.m.jones@btinternet.com>; Austin, Christopher (NIH/NCATS) [E] (b) (6); geoff@ptbusinessgroups.com
Subject: RE: Hever agenda

Dear Dr Collins

I have updated the agenda to give you another half hour by cutting 15 minutes of the morning break and lunch. I hope that this is sufficient time for you.

Kind regards

Jill Payne
On behalf of Hever

Email: jill@ptbusinessgroups.com
Cell: (b) (6)

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From: Collins, Francis (NIH/OD) [E] (b) (6)
Sent: 11 April 2018 00:03
To: MD Paul Stoffels
Cc: Jill Payne; Prof Trevor M Jones CBE FMedSci; Austin, Christopher (NIH/NCATS) [E]
Subject: Hever agenda

Hi Paul,

I've been preparing for the "NIH update" session at Hever 23 this coming Saturday morning – and I'm concerned that the assigned 45-minute time slot may make it very difficult to turn this into a productive segment with appropriate time for discussion. As per the agenda (attached), I am to discuss AMP (including four sub-projects), the PACT public-private partnership on cancer immunotherapy, the opioids/pain PPP that was birthed last year at Hever, and the Coalition for African Research and Innovation (CARI) that will have new information from Friday's inventory call. I also think it's critical for me to give a quick heads up to the Heverites about the imminent launch of the *All of Us* million-person American cohort, given its potential to revolutionize clinical trial enrollment. That makes five meaty topics, for all of which there are timely questions for discussion that I had hoped to tee up.

With apologies for asking so late in the game, is there any chance that more time could be assigned to this session?

Thanks for considering,

Francis

This email has been scanned by iomartcloud.
http://www.iomartcloud.com

From: Wholley, David (FNIH) [T]
Sent: Mon, 16 Apr 2018 15:09:56 +0000
To: Collins, Francis (NIH/OD) [E]
Subject: RE: Materials for the PACT NIH/NCI Update - April 17th

Just wondering how Hever went…

From: Collins, Francis (NIH/OD) [E]
Sent: Sunday, April 15, 2018 5:54 PM
To: Adam, Stacey (FNIH) [T] <sadam@fnih.org>; Sharpless, Norman (NIH/NCI) [E] (b) (6); Doroshow, James (NIH/NCI) [E] (b) (6); Baker, Rebecca (NIH/OD) [E] (b) (6)
Cc: McManus, Ayanna (NIH/OD) [E] (b) (6); Wood, Gretchen (NIH/OD) [E] (b) (6); Sapaula, Tessa (NIH/NCI) [C] (b) (6) Pak, Hannah (NIH/NCI) [E] (b) (6); Peterson-Klaus, Jenny (FNIH) [T] <jpeterson-klaus@fnih.org>; Wholley, David (FNIH) [T] <dwholley@fnih.org>; Melencio, Cheryl (FNIH) [T] <cmelencio@fnih.org>
Subject: RE: Materials for the PACT NIH/NCI Update - April 17th

Looks like a good plan to me.

FC

From: Adam, Stacey (FNIH) [T]
Sent: Friday, April 13, 2018 4:30 PM
To: Collins, Francis (NIH/OD) [E] (b) (6); Sharpless, Norman (NIH/NCI) [E] (b) (6); Doroshow, James (NIH/NCI) [E] (b) (6)>; Baker, Rebecca (NIH/OD) [E] (b) (6)
Cc: McManus, Ayanna (NIH/OD) [E] (b) (6); Wood, Gretchen (NIH/OD) [E] (b) (6); Sapaula, Tessa (NIH/NCI) [C] (b) (6); Pak, Hannah (NIH/NCI) [E] (b) (6); Peterson-Klaus, Jenny (FNIH) [T] <jpeterson-klaus@fnih.org>; Wholley, David (FNIH) [T] <dwholley@fnih.org>; Melencio, Cheryl (FNIH) [T] <cmelencio@fnih.org>
Subject: Materials for the PACT NIH/NCI Update - April 17th

Dear NIH and NCI PACT Colleagues,

Thank you so much for working with us to arrange a new time for our usually monthly update.

Given we have moved this meeting up so it takes place before our first PACT quarterly EC call, we thought it would be best to focus our discussion on Tuesday evening on the agenda (and if needed the slides) for the EC meeting planned for Thursday night (April 19) from 7-8 pm ET. We thought it would be best to get this team's thoughts on the agenda before we distributed it to the wider group.

The agenda and the suggested slides are attached to this email for your review. Please let us know if you have any suggestions ahead of our meeting on Tuesday. Otherwise, we can discuss them on the call.

Also, please let us know if you have any other topics you feel we need to address in our Tuesday meeting other than the EC meeting. We would be happy to add them to our discussion plans.

As always, if you have any questions, please do not hesitate to reach out to David or myself.

Thanks,
Stacey

Stacey J. Adam, PhD
Scientific Program Manager, Cancer
Foundation for the National Institutes of Health
Direct: **(301) 435-8364** | Mobile: (b) (6)
fnih.org
11400 Rockville Pike Suite 600 North Bethesda, MD 20852

2017 Gold Stevie Award Winner for Organization of the Year

From: Wholley, David (FNIH) [T]
Sent: Mon, 16 Apr 2018 17:09:27 +0000
To: Koroshetz, Walter (NIH/NINDS) [E];Volkow, Nora (NIH/NIDA) [E]
Cc: Baker, Rebecca (NIH/OD) [E];Collins, Francis (NIH/OD) [E];Melencio, Cheryl (FNIH) [T];Menetski, Joseph (FNIH) [T];Biarnes, Michael (FNIH) [T]
Subject: RE: Opioids Governance Discussion

Thanks, Walter.

From: Koroshetz, Walter (NIH/NINDS) [E]
Sent: Monday, April 16, 2018 1:07 PM
To: Wholley, David (FNIH) [T] <dwholley@fnih.org>; Volkow, Nora (NIH/NIDA) [E] <nvolkow@nida.nih.gov>
Cc: Baker, Rebecca (NIH/OD) [E] (b) (6); Collins, Francis (NIH/OD) [E] (b) (6); Melencio, Cheryl (FNIH) [T] <cmelencio@fnih.org>; Menetski, Joseph (FNIH) [T] <jmenetski@fnih.org>; Biarnes, Michael (FNIH) [T] <mbiarnes@fnih.org>
Subject: RE: Opioids Governance Discussion

Thanks David. (b) (5) Others as schedule allows. Locations all good for me.
walter

From: Wholley, David (FNIH) [T]
Sent: Monday, April 16, 2018 12:31 PM
To: Volkow, Nora (NIH/NIDA) [E] (b) (6); Koroshetz, Walter (NIH/NINDS) [E] (b) (6)
Cc: Baker, Rebecca (NIH/OD) [E] (b) (6); Collins, Francis (NIH/OD) [E] (b) (6); Melencio, Cheryl (FNIH) [T] <cmelencio@fnih.org>; Menetski, Joseph (FNIH) [T] <jmenetski@fnih.org>; Biarnes, Michael (FNIH) [T] <mbiarnes@fnih.org>
Subject: FW: Opioids Governance Discussion

Dear Walter and Nora:

Please see the list of folks who were involved in the opioids partnership Working Groups from NIH. As we discussed on Thursday, we need to convene a meeting asap to lay out a proposed governance structure and related next steps for the partnership, with appropriate NIH policy input. Can you please give me your input on whom should be invited to this meeting so Cheryl can start working the calendars? Myself, Mike Biarnes, and Joe Menetski will attend from FNIH.

Also would appreciate your input on venue. We are happy to host a meeting here at FNIH (our offices are convenient to the main NIH campus and other offices as we are two blocks south of White Flint metro at 11400 Rockville Pike) or we can do on NIH campus if you would prefer, and can find us a room.

Thanks, David

Nora Volkow – NIDA
Walter Koroshetz – NINDS
Linda Porter – NINDS
Chris Austin and/or Christine Colvis – NCATS
Jack Stein - NIDA
Rebecca Baker - NIH

Optional Co-Chairs
Clinton Wright – NINDS
Dave Thomas – NIDA
Michael Oshinsky - NINDS

Do you think that it would beneficial to have FDA represented at this meeting as well?

Thanks,
Mike

Michael Biarnes
Scientific Project Manager
Foundation for the National Institutes of Health
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11400 Rockville Pike Suite 600 North Bethesda, MD 20852

2017 Gold Stevie Award Winner for Organization of the Year

From: Wholley, David (FNIH) [T]
Sent: Tue, 17 Apr 2018 22:26:09 +0000
To: Collins, Francis (NIH/OD) [E]
Subject: Very quick question

(b) (5)

(b) (5) Thanks

Sent from my BlackBerry 10 smartphone.

From: Wholley, David (FNIH) [T]
Sent: Sun, 1 Apr 2018 14:12:54 +0000
To: Collins, Francis (NIH/OD) [E];Sharpless, Norman (NIH/NCI) [E];Doroshow, James (NIH/NCI) [E];Axel Hoos;perez.edith@gene.com;thomas.hudson@abbvie.com
Cc: Marks, Peter (FDA/CBER);Pazdur, Richard (FDA/OC)
Subject: (b) (5)
Committee

Dear PACT Executive Committee members: (b) (5)

(b) (5)

(b) (5) We will make sure it is on the agenda.

Thank you for your quick response on this issue.

David

David Wholley
Director, Research Partnerships
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(301) 594-6343
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11400 Rockville Pike Suite 600 North Bethesda, MD 20852

2017 Gold Stevie Award Winner for Organization of the Year

From: Wholley, David (FNIH) [T]
Sent: Fri, 13 Apr 2018 16:16:07 +0000
To: Collins, Francis (NIH/OD) [E]
Subject: a quote from today's AMP T2D telecon

Francis –
As you head up to New York for Hever I just wanted to share one statement I heard verbatim from one of the industry executive leads on the AMP T2D Steering Committee whom I particularly respect, related to the need to begin allowing the sharing and ability to perform integrated queries across multiple diseases and phenotypes. I think it summarized very eloquently the concerns of the entire group:

(b) (5)

Thanks for your help on dbGaP. I spoke to Laura Rodriguez this morning and it sounds like we might be getting near(er) to a solution on that thanks to what sounds like a lot of hard work. Fingers crossed.

David

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2017 Gold Stevie Award Winner for Organization of the Year

From: Wholley, David (FNIH) [T]
Sent: Fri, 20 Apr 2018 18:24:44 +0000
To: Collins, Francis (NIH/OD) [E];Tabak, Lawrence (NIH/OD) [E]
Cc: McManus, Ayanna (NIH/OD) [E];Wood, Gretchen (NIH/OD) [E];Boskent, Celeste (NIH/OD) [E];Melencio, Cheryl (FNIH) [T];Morgan, Emily (FNIH) [T]
Subject: AMP EC -- April 27 vs May 4 2018.xlsx
Attachments: AMP EC -- April 27 vs May 4 2018.xlsx

Francis and Larry:
Good news on rescheduling the AMP EC from April 27 to 7AM Friday May 4 as requested, I think. We have two NIH Directors we've not heard from yet – Griff Rodgers and Walter Koroshetz—and Richard Hodes will be on a plane. (Larry I trust from our conversation yesterday you can attend?) Jan Lundberg is still out (though he'd have missed next Friday anyway). But Mikael Dolsten and Paul Stoffels have reconfirmed they can make 5/4, and we have at least one co-chair confirmed from each of the four disease/therapeutic SCs. I suggest we move forward with the change to May 4.

Can your office please confirm, and copy Cheryl Melencio and Emily Morgan? Thanks, David

	A	B	C	D
1	Name	Attendance	27-Apr	4-May
2	Berlyne, Debby (science writer)	Required Attendee	Accepted	
3	Canet-Aviles, Rosa (FNIH) [T]	Required Attendee	Accepted	yes
4	Carter, Robert (NIH/NIAMS) [E]	Required Attendee	Accepted	Yes
5	Collier, David	Required Attendee	Accepted	Yes
6	Collins, Francis (NIH/OD) [E]	Required Attendee	Accepted	Yes
7	Dolsten, Mikael	Required Attendee	Accepted	Yes
8	Fischer, Tanya	Required Attendee	Accepted	Yes
9	Gadbois, Ellen (NIH/OD) [E]	Required Attendee	Accepted	
10	Hodes, Richard (NIH/NIA) [E]	Required Attendee	Accepted	No on plane
11	Hodge, Martin	Required Attendee	Accepted	Yes
12	Hoffmann, Steve (FNIH) [T]	Required Attendee	Accepted	yes
13	Kamphaus, Tania (FNIH) [T]	Required Attendee	Accepted	yes
14	Katz, Stephen I. (NIH/NIAMS) [E]	Required Attendee	Accepted	Yes
15	Koroshetz, Walter (NIH/NINDS) [E]	Required Attendee	Tentative	
16	Lifton, Richard	Required Attendee	Accepted	Yes
17	Lundberg, Jan	Required Attendee	Declined	No
18	Melencio, Cheryl (FNIH) [T]	Meeting Organizer	None	yes
19	Menetski, Joseph (FNIH) [T]	Required Attendee	Accepted	yes
20	Paltoo, Dina (NIH/OD) [E]	Required Attendee	Accepted	
21	Petanceska, Suzana (NIH/NIA) [E]	Required Attendee	None	yes
22	Rodgers, Griffin (NIH/NIDDK) [E]	Required Attendee	Accepted	
23	Ryan, Laurie (NIH/NIA) [E]	Required Attendee	None	yes
24	Serrate-Sztein, Susana (NIH/NIAMS) [E]	Required Attendee	None	
25	Singh, Jyoti (NIH/OD) [E]	Required Attendee	Accepted	
26	Smith, Philip (NIH/NIDDK) [E]	Required Attendee	Accepted	yes
27	Stoffels, Paul	Required Attendee	Accepted	Yes
28	Sutherland, Margaret (NIH/NINDS) [E]	Required Attendee	Accepted	Yes
29	Tabak, Lawrence (NIH/OD) [E]	Required Attendee	None	
30	Terry, Sharon	Required Attendee	Tentative	Yes
31	Thomas, Melissa	Required Attendee	Accepted	
32	Wholley, David (FNIH) [T]	Required Attendee	Accepted	yes

From: Wholley, David (FNIH) [T]
Sent: Thu, 5 Apr 2018 17:26:59 +0000
To: Collins, Francis (NIH/OD) [E];Tabak, Lawrence (NIH/OD) [E];Volkow, Nora (NIH/NIDA) [E];Koroshetz, Walter (NIH/NINDS) [E];Stein, Jack (NIH/NIDA) [E];Porter, Linda (NIH/NINDS) [E];Wolinetz, Carrie (NIH/OD) [E];Baker, Rebecca (NIH/OD) [E];Shapiro, Neil (NIH/OD) [E]
Cc: Menetski, Joseph (FNIH) [T];Biarnes, Michael (FNIH) [T]
Subject: budget from opioids white paper
Attachments: Opioid White Paper budget from final version 2-12-18.docx

As requested

David Wholley
Director, Research Partnerships
Foundation for the National Institutes of Health
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11400 Rockville Pike Suite 600 North Bethesda, MD 20852

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I. Overall Budget

The following tables summarize 1) the base budget investments required to deliver on the goals of the partnership and 2) the budget for additional "optimal" investments that have been identified as adding significantly to the value proposition of the partnership in specific solutions areas.

NIH - 004694

(b) (5)

(b) (5)

NIH - 004697

From: Wholley, David (FNIH) [T]
Sent: Mon, 9 Apr 2018 14:04:04 +0000
To: Collins, Francis (NIH/OD) [E]
Subject: DbGaP and AMP T2D portal

Francis,
Continuing to follow up from our brief discussion at the FNIH Board meeting, I have another request for your consideration. (b) (5)

(b) (5)

(b) (5)

Thank you again Francis for being willing to listen to these ideas.

David

David Wholley
Director, Research Partnerships
Foundation for the National Institutes of Health
(301) 594-6343
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2017 Gold Stevie Award Winner for Organization of the Year

From: Wholley, David (FNIH) [T]
Sent: Fri, 6 Apr 2018 16:53:59 +0000
To: Collins, Francis (NIH/OD) [E]
Subject: Discussion of IMI SUMMIT data at the Hever meeting

Francis:
You may remember that at the FNIH Board meeting a few weeks back I briefly mentioned to you several issues related to enhancing the AMP T2D portal on which I could use your help. (b) (5)

(b) (5)

[redacted] (b) (5)

Thanks for agreeing to discuss this. Please let me know if you need any additional information.
Thanks, David

[redacted] David Wholley
Director, Research Partnerships
Foundation for the National Institutes of Health
(301) 594-6343
fnih.org
11400 Rockville Pike Suite 600 North Bethesda, MD 20852

2017 Gold Stevie Award Winner for Organization of the Year

From: Wholley, David (FNIH) [T]
Sent: Thu, 12 Apr 2018 14:45:08 +0000
To: Collins, Francis (NIH/OD) [E];Tabak, Lawrence (NIH/OD) [E];Volkow, Nora (NIH/NIDA) [E];Koroshetz, Walter (NIH/NINDS) [E];Stein, Jack (NIH/NIDA) [E];Porter, Linda (NIH/NINDS) [E];Wolinetz, Carrie (NIH/OD) [E];Baker, Rebecca (NIH/OD) [E]
Cc: Menetski, Joseph (FNIH) [T];Melencio, Cheryl (FNIH) [T]
Subject: FW: Opioid Partnership Update

For your information, please see the note that we sent to the Opioid Partnership Working Group members this morning. Thanks, David

---

From: Biarnes, Michael (FNIH) [T]
Sent: Thursday, April 12, 2018 9:41 AM
To: Ahadpour, Mitra (FDA/CDER) (b) (6); Ahn, Andy <andyahn@lilly.com>; Austin, Christopher (NIH/NCATS) [E] (b) (6); Baker, Rebecca (NIH/OD) [E] (b) (6); Balice-Gordon, Rita <Rita.Balice-Gordon@sanofi.com>; Beebe, Katherine <kbeebe@titanpharm.com>; Biarnes, Michael (FNIH) [T] <mbiarnes@fnih.org>; David Borsook <david.borsook@childrens.harvard.edu>; Braunstein, Ned <ned.braunstein@regeneron.com>; Burczynski, Michael <michael.burczynski@tevapharm.com>; Chang, Nancy (FDA/CDER) (b) (6); Chin, Bill <chin@phrma.org>; Colvis, Christine (NIH/NCATS) [E] (b) (6) Cyrus, Pam <pam.cyrus@bayer.com>; Dawson, Kate <kate.dawson@biogen.com>; Debar, Lynn <debar.l@ghc.org>; Doberstein, Steve <sdoberstein@nektar.com>; Dolmetsch, Ricardo <ricardo.dolmetsch@novartis.com>; Dunbar, Stephanie <stephanie.dunbar@tevapharm.com>; Dunlop, John <jdunlop@amgen.com>; Dworkin, Robert <robert_dworkin@urmc.rochester.edu>; Fields, Ellen (FDA/CDER) (b) (6); Flores, Chris <cflores2@its.jnj.com>; Sheri Grabus <sgrabus@iqsolutions.com>; Hachicha, Mohamed (NIH/NINDS) [E] (b) (6); Haeberlein, Markus <markus.haeberlein@alkermes.com>; Hammock, Bruce <bdhammock@ucdavis.edu>; Han, Steve X. <steve.x.han@gsk.com>; Hepker, Jen <jhepker@prescottmed.com>; Hertz, Sharon H (FDA/CDER) (b) (6); Holenz, Joerg <joerg.x.holenz@gsk.com>; Kehne, John (NIH/NINDS) [E] (b) (6); Koblan, Kenneth <kenneth.koblan@sunovion.com>; Kopecky, Ernest <ernest.kopecky@tevapharm.com>; Koroshetz, Walter (NIH/NINDS) [E] (b) (6) Kramer, Mike <mkramer@trevena.com>; Kyle, Don <don.kyle@pharma.com>; Laurenza, Antonio <antonio_laurenza@eisai.com>; Lefevre, Isabel <isabel.lefevre@sanofi.com>; Li, Min <min.x.li@gsk.com>; Lin, Allison (FDA/CDER) (b) (6); Malamut, Richard <rmalamut@avanir.com>; Mannion, Richard <richard.mannion@pharma.com>; Marek, Gerard <gerard.marek@astellas.com>; Jennifer McCulley <jmcculley@iqsolutions.com>; McManus, Owen <owen.mcmanus@qstatebio.com>; Menetski, Joseph (FNIH) [T] <jmenetski@fnih.org>; Mintun, Mark <mintun@avidrp.com>; Moscicki, Rich <rmoscicki@phrma.org>; Mullins, Christopher (NIH/NIDDK) [E] (b) (6); Oshinsky, Michael (NIH/NINDS) [E] (b) (6); Patel, Vickas <vickas.x.patel@gsk.com>; Pelleymounter, Mary (NIH/NINDS) [E] (b) (6); Porter, Linda (NIH/NINDS) [E] (b) (6); Powers, Scott <scott.powers@cchmc.org>; Predescu, Alina (NIH/NCATS) [E] (b) (6); Ramey, Tanya (NIH/NIDA) [E] (b) (6); Rosen, Laura <laura.rosen@takeda.com>; Sandrock, Alfred <alfred.sandrock@biogen.com>; Schmidt, William <schmidtwk@sbcglobal.net>; Stein, Jack (NIH/NIDA) [E] (b) (6)>; Sullivan, James <james.p.sullivan@abbvie.com>; Szegedi, Armin

<armin.szegedi@allergan.com>; Tamiz, Amir (NIH/NINDS) [E] (b) (6); Thomas, David (NIH/NIDA) [E] (b) (6); Tilly, Jason <jason.tilly@mallinckrodt.com>; Tollemar, Ulf <ulf.tollemar@astellas.com>; Truitt, ken <ktruitt@dsi.com>; Uz, Tolga <tolga.uz@astellas.com>; Vallejo, Yolanda (NIH/NIDCR) [E] (b) (6); Verburg, Kenneth <kenneth.m.verburg@pfizer.com>; Wager, Tor (b) (6); Weinreich, David <david.weinreich@regeneron.com>; Wholley, David (FNIH) [T] <dwholley@fnih.org>; Woolf, Clifford <clifford.woolf@childrens.harvard.edu>; Wright, Clinton (NIH/NINDS) [E] <clinton.wright@nih.gov>; Zorn, Stevin <zornsh@mindimmune.com>
Cc: Chow, Tina <tina.chow@novartis.com>; Colfax, Tracey <tcolfax@its.jnj.com>; Finnegan, Sean (NIH/NCATS) [E] (b) (6); Henrique, Gleise <gleiseh@amgen.com>; Koch, Kellie <kkoch@phrma.org>; Kruzik, Nan <kruzik@avidrp.com>; Plantinga, Karen <karen.plantinga@sanofi.com>; Regan, Donna <Donna.regan@abbvie.com>; Waltzer, Renee (NIH/NINDS) [C] (b) (6)
Subject: Opioid Partnership Update

Dear Opioid Partnership Working Group Members:

In case you have not seen them, I am forwarding for your information links to the recommendations of a Working Group to the Advisory Committee to Director (ACD) of the NIH which were discussed at a meeting of the ACD held this past Friday, April 6, regarding the funding and structure of a potential partnership to address the opioid crisis. I am also including two pieces of correspondence between our FNIH President, Maria Freire, and Deputy NIH Director Larry Tabak related to a separate discussion of these same issues conducted by the FNIH Board on March 30.

While the outcome of the FNIH Board's discussions is known, formal acceptance of and action on the ACD recommendations are the responsibility of the NIH Director. Although I cannot comment specifically on what NIH may decide, I think it is worth pointing out in connection with this situation the fact that the Congress has recently approved $500M in funding for NIH to be spent through fiscal year 2019 on initiatives to address the opioid crisis, and that there is latitude within both the FNIH and ACD recommendations for conducting a partnership within specific limitations. I would add to that my sense that there continues to be high enthusiasm for advancing the scientific goals outlined for such a partnership in the white paper, to which you all contributed your valuable time and insights. I will be sure to let you know more about the outcome of the NIH decision process as soon as we hear more.

Regards,
David Wholley

https://acd.od.nih.gov/documents/presentations/032018_opioids-draft-report.pdf

https://acd.od.nih.gov/documents/presentations/04062018presentation.pdf

NIH Letter to FNIH

FNIH Response to NIH

From: Wholley, David (FNIH) [T]
Sent: Mon, 16 Apr 2018 16:30:57 +0000
To: Volkow, Nora (NIH/NIDA) [E];Koroshetz, Walter (NIH/NINDS) [E]
Cc: Baker, Rebecca (NIH/OD) [E];Collins, Francis (NIH/OD) [E];Melencio, Cheryl (FNIH) [T];Menetski, Joseph (FNIH) [T];Biarnes, Michael (FNIH) [T]
Subject: FW: Opioids Governance Discussion

Dear Walter and Nora:

Please see the list of folks who were involved in the opioids partnership Working Groups from NIH. As we discussed on Thursday, we need to convene a meeting asap to lay out a proposed governance structure and related next steps for the partnership, with appropriate NIH policy input. Can you please give me your input on whom should be invited to this meeting so Cheryl can start working the calendars? Myself, Mike Biarnes, and Joe Menetski will attend from FNIH.

Also would appreciate your input on venue. We are happy to host a meeting here at FNIH (our offices are convenient to the main NIH campus and other offices as we are two blocks south of White Flint metro at 11400 Rockville Pike) or we can do on NIH campus if you would prefer, and can find us a room.

Thanks, David

Nora Volkow – NIDA
Walter Koroshetz – NINDS
Linda Porter – NINDS
Chris Austin and/or Christine Colvis – NCATS
Jack Stein - NIDA
Rebecca Baker - NIH

Optional Co-Chairs
Clinton Wright – NINDS
Dave Thomas – NIDA
Michael Oshinsky - NINDS

Do you think that it would beneficial to have FDA represented at this meeting as well?

Thanks,
Mike

Michael Biarnes
Scientific Project Manager
Foundation for the National Institutes of Health
(301) 594-2612
fnih.org
11400 Rockville Pike Suite 600 North Bethesda, MD 20852

2017 Gold Stevie Award Winner for Organization of the Year

From: Wholley, David (FNIH) [T]
Sent: Thu, 23 Oct 2014 13:01:24 -0400
To: Collins, Francis (NIH/OD) [E]
Subject: Fw: AMP Alzheimer's disease research plan and (b) (4)

----- Original Message -----
From: Wholley, David (FNIH) [T]
Sent: Thursday, October 23, 2014 12:41 PM
To: Hodes, Richard (NIH/NIA) [E]; Buckholtz, Neil (NIH/NIA) [E]; (b) (6) (b) (6)
Subject: Fw: AMP Alzheimer's disease research plan and (b) (4)

FYI.

----- Original Message -----
From: Wholley, David (FNIH) [T]
Sent: Thursday, October 23, 2014 10:20 AM
To: (b) (4)
Cc: Canet-Aviles, Rosa (FNIH) [T]; Wolf-Rodda, Julie (FNIH) [T]
Subject: Re: AMP Alzheimer's disease research plan and (b) (4)

Thanks. (b) (4) Thanks very much for taking this up the line for us.

David Wholley

----- Original Message -----
From: (b) (4)
Sent: Thursday, October 23, 2014 12:16 AM
To: Wholley, David (FNIH) [T]
Subject: RE: AMP Alzheimer's disease research plan and (b) (4)

Dear David,
After our AMP AD discussion last month (b) (4)
(b) (4)
Thanks
(b) (4)

-----Original Message-----
From: Canet-Aviles, Rosa (FNIH) [T] [mailto:rcanet-aviles@fnih.org]
Sent: Thursday, September 25, 2014 10:01 PM
To: (b) (4)
Cc: Melencio, Cheryl (FNIH) [T]; Acland, Emily (FNIH) [T]; Wholley, David (FNIH) [T]; Wolf-Rodda, Julie (FNIH) [T]; Bante, Jillian (FNIH) [T]
Subject: Materials for next Monday's call re. AMP Alzheimer's disease research plan and (b) (4)

Please, find the slides attached that will help guide our discussion next Monday.

Best,
Rosa

Rosa M Canet-Avilés, PhD
Scientific Program Manager, Neuroscience Research Partnerships Foundation for the National Institutes of Health

9650 Rockville Pike | Bethesda, MD 20814 | www.fnih.org<http://www.fnih.org/>
Direct (b) (6) | Cell phone (b) (6) | (b) (6)
[FNIH-LOGO-2013_4x2in_RGB-with-TRANSP]

From: Wholley, David (FNIH) [T]
Sent: Mon, 2 Jun 2014 22:48:49 -0400
To: Collins, Francis (NIH/OD) [E]
Cc: Hudson, Kathy (NIH/OD) [E];Gadbois, Ellen (NIH/OD) [E]
Subject: Re: Today's CEOi/Sage Open Science/Big Data Challenge Announcement

Francis,
I'll double check with AD colleagues but there is no direct link I know of: (b) (5)

(b) (5)

David

From: Collins, Francis (NIH/OD) [E]
Sent: Monday, June 02, 2014 07:59 PM
To: Wholley, David (FNIH) [T]
Cc: Hudson, Kathy (NIH/OD) [E]; Gadbois, Ellen (NIH/OD) [E]
Subject: FW: Today's CEOi/Sage Open Science/Big Data Challenge Announcement

Hi David,

(b) (5)

Tx, FC

From: (b) (6)
Sent: Monday, June 02, 2014 12:41 PM
To: Collins, Francis (NIH/OD) [E]; Hodes, Richard (NIH/NIA) [E]; Woodcock, Janet (FDA/CDER)
Cc: debra.lappin@faegrebd.com; (b) (6)
Subject: Today's CEOi/Sage Open Science/Big Data Challenge Announcement

I thought you would be interested in this.

Thanks for all of your efforts in Alzheimer's.

George

From: Wholley, David (FNIH) [T]
Sent: Sat, 1 Feb 2014 14:25:24 -0500
To: Burklow, John (NIH/OD) [E];Collins, Francis (NIH/OD) [E];Devaney, Stephanie (NIH/OD) [E];Myles, Renate (NIH/OD) [E]
Subject: Re: Monica's latest note--

(b) (5)

David

From: Burklow, John (NIH/OD) [E]
Sent: Saturday, February 01, 2014 01:31 PM
To: Collins, Francis (NIH/OD) [E]; Wholley, David (FNIH) [T]; Devaney, Stephanie (NIH/OD) [E]; Myles, Renate (NIH/OD) [E]
Subject: Monica's latest note--

Need to know how much in-kind and how much foundations..we are NOT squishy with numbers in the WSJ!

John Burklow
Associate Director for Communications and Public Liaison
National Institutes of Health
Building (b) Room (b)
(b) (6) (phone)
(301) 496-0017 (fax)
(b) (6)

NIH . . . *Turning Discovery Into Health®*

Celebration of Science at NIH: *watch how medical research saves lives and improves health*

From: Wholley, David (FNIH) [T]
Sent: Sat, 1 Feb 2014 16:44:37 -0500
To: Collins, Francis (NIH/OD) [E];Burklow, John (NIH/OD) [E]
Cc: Devaney, Stephanie (NIH/OD) [E];Myles, Renate (NIH/OD) [E]
Subject: Re: Monica's take--

Francis said it better, as usual

From: Collins, Francis (NIH/OD) [E]
Sent: Saturday, February 01, 2014 04:37 PM
To: Burklow, John (NIH/OD) [E]
Cc: Wholley, David (FNIH) [T]; Devaney, Stephanie (NIH/OD) [E]; Myles, Renate (NIH/OD) [E]
Subject: RE: Monica's take--

Maybe this will help:

The data will be accessible to all, so we actually hope the companies will be using it as soon as it's generated. "Going off to make drugs sooner" is not a risk, it's a desirable outcome.

As for providing data they are supposed to share, the companies have all signed on to the project design plans. Those make it very clear what's included. The disease-specific project teams will be watching for any reticence to share, and the Steering Committee will oversee the whole endeavor. But ultimately, AMP will rest on a foundation of mutual respect and trust.

FC

From: Burklow, John (NIH/OD) [E]
Sent: Saturday, February 01, 2014 4:32 PM
To: Collins, Francis (NIH/OD) [E]
Cc: Wholley, David (FNIH) [T]; Devaney, Stephanie (NIH/OD) [E]; Myles, Renate (NIH/OD) [E]
Subject: Re: Monica's take--

The latest request from Monica--David, anything else I can say?

Thanks,

John

(b) (5)

John Burklow
Associate Director for Communications and Public Liaison
National Institutes of Health
Building (b) (6) Room (b) (6)

(b) (6) (phone)
(301) 496-0017 (fax)
(b) (6)

NIH . . . *Turning Discovery Into Health®*

Celebration of Science at NIH: *watch how medical research saves lives and improves health*

On Feb 1, 2014, at 4:09 PM, "Collins, Francis (NIH/OD) [E]" (b) (6) wrote:

Are we all having fun on Saturday? ☺

From: Burklow, John (NIH/OD) [E]
Sent: Saturday, February 01, 2014 4:04 PM
To: Collins, Francis (NIH/OD) [E]
Cc: Wholley, David (FNIH) [T]; Devaney, Stephanie (NIH/OD) [E]; Myles, Renate (NIH/OD) [E]
Subject: Re: Monica's take--

Thanks!

John Burklow
Associate Director for Communications and Public Liaison
National Institutes of Health
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(b) (6) (phone)
(301) 496-0017 (fax)
(b) (6)

NIH . . . *Turning Discovery Into Health®*

Celebration of Science at NIH: *watch how medical research saves lives and improves health*

On Feb 1, 2014, at 4:02 PM, "Collins, Francis (NIH/OD) [E]" (b) (6)> wrote:

They will be at the table, and providing input about patient perspectives on how priorities for the projects are set.

From: Burklow, John (NIH/OD) [E]
Sent: Saturday, February 01, 2014 3:17 PM
To: Collins, Francis (NIH/OD) [E]
Cc: Wholley, David (FNIH) [T]; Devaney, Stephanie (NIH/OD) [E]; Myles, Renate (NIH/OD) [E]
Subject: Re: Monica's take--

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Sent: Sat, 1 Feb 2014 16:43:47 -0500
To: Burklow, John (NIH/OD) [E];Collins, Francis (NIH/OD) [E]
Cc: Devaney, Stephanie (NIH/OD) [E];Myles, Renate (NIH/OD) [E]
Subject: Re: Monica's take--

[redacted] (b) (4)

[redacted] (b) (4) I don't know what else to say.

From: Burklow, John (NIH/OD) [E]
Sent: Saturday, February 01, 2014 04:32 PM
To: Collins, Francis (NIH/OD) [E]
Cc: Wholley, David (FNIH) [T]; Devaney, Stephanie (NIH/OD) [E]; Myles, Renate (NIH/OD) [E]
Subject: Re: Monica's take--

The latest request from Monica--David, anything else I can say?

Thanks,

John

[redacted] (b) (5)

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Geoffrey Beene Fdn
American Diabetes Assn
Rheumatology Research Fdn
Lupus Fdn of America

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From: Wholley, David (FNIH) [T]
Sent: Sat, 1 Feb 2014 16:50:47 -0500
To: Collins, Francis (NIH/OD) [E]
Subject: Re: Monica's take--

Yes sorry we did indeed give Renate the correct name as Us Against Alzheimer's--I had to ask George though because he signed his funding agreement as Vradenburg Fdn. I was not sure if you were putting PhRMA in the industry camp or the non-profits but yes they should be mentioned for sure

---

From: Collins, Francis (NIH/OD) [E]
Sent: Saturday, February 01, 2014 04:42 PM
To: Wholley, David (FNIH) [T]; Burklow, John (NIH/OD) [E]
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Subject: RE: Monica's take--

Don't forget PhRMA.

And isn't the Vradenburg Fdn really called UsAgainstAlzheimers?

From: Wholley, David (FNIH) [T]
Sent: Saturday, February 01, 2014 4:36 PM
To: Burklow, John (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]
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